TECHNICAL SUMMARY
FINANCIAL MANAGEMENT PROFILE
OF THE
FOOD AND DRUG ADMINISTRATION

PREPARED
BY THE STAFF
OF THE
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Foreword

The Food and Drug Administration is an organizational component of the Department of Health and Human Services. In fiscal 1982 it received approximately \$378 million in budget authority. The Food and Drug Administration is responsible for regulating the purity, quality, and content of food (including food additives), color additives, human and animal drugs (including medicated animal feeds), medical devices and cosmetics. In addition, the Food and Drug Administration regulates products in interstate commerce as well as those imported.

This technical summary is one of 11 volumes of detailed information that supports the overall Financial Management Profile for the Department of Health and Human Services (AFMD 84-15, April 9, 1984). The technical summaries provide detailed information on the major organization components of the Department of Health and Human Services (the Department), their financial management systems, and major internal control strengths and weaknesses in these systems.

The financial management profile of the Department and the 11 technical summaries were prepared by GAO as a pilot test of a new audit approach—called Controls and Risk Evaluation (CARE)—for (1) identifying and describing the financial management systems used by an agency and (2) assessing and ranking the internal control strengths and weaknesses of the systems. This analysis is based on reviews of available systems documentation, discussions with agency personnel, and reviews of prior GAO and Inspector General reports. Tests were not performed on actual information processed by and recorded in the systems, therefore, conclusions cannot be reached about whether the system's internal controls were actually operating as designed.

The information in this technical summary is intended for use in:

- --planning future tests and evaluations of the accounting and financial management systems at the Food and Drug Administration,
- --monitoring the Administration's efforts to implement the Federal Managers' Financial Integrity Act of 1982, and
- --supporting and enhancing the understanding and application of the CARE-based methodology by designers, operators, and evaluators of agency accounting and financial management systems.

The profile provides a description of the financial management structure of the Food and Drug Administration. Six financial management systems form the financial management structure of the Administration. These systems are used to (1) control appropriated funds and other resources, (2) authorize the use of funds and other

resources, and (3) capture, record, process, and summarize financial information related to the execution of budget authority. The summary also provides a detailed analysis of the systems and identifies specific internal control strengths and weaknesses for each system.

During the course of GAO's survey agency officials were briefed. The profile was provided to cognizant agency officials for their review and comments. Agency comments were considered and changes were made as appropriate. The assistance and cooperation of agency management enhanced the successful completion of the work. The results of the survey will be used by GAO as the basis for planning future reviews of the Food and Drug Administration's financial management systems to ascertain if they conform to the Comptroller General's principles and standards for federal agencies. The profile is being provided to the Administration to assist it in its continuing efforts to improve financial management.

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FOOD AND DRUG ADMINISTRATION -- ITS RESPONSIBILITIES,

ACTIVITIES, AND FINANCIAL MANAGEMENT STRUCTURE

The Food and Drug Administration (FDA) is a major consumer protection agency in the federal government. FDA received \$378 million in fiscal 1982 budget authority and employed about 7,300 individuals. Based upon our review and analysis of available documentation and through discussions with agency personnel, we determined that FDA's financial management structure is composed of six automated systems. These systems, taken together, authorize payments, control assets and liabilities, record and control receipts, and provide for administrative control of FDA's spending authority and produce internal and external financial reports.

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In assessing the internal control strengths and weaknesses of the FDA accounting general ledger/administrative control of funds system, we determined that the controls appeared adequate to ensure that the financial results of program and administrative operations are completely and accurately recorded and reported and that FDA's spending authority is not breached.

We also found, however, that FDA was operating duplicate financial management systems and that neither Bureaus nor the field offices were processing financial information in the most economic and efficient manner. FDA is aware of these problems and has initiated corrective actions.

The objectives, scope, and methodology of our survey are discussed in appendix I. Appendix II contains the internal control strengths and weaknesses we identified in the FDA Umbrella Accounting System, and appendix III contains a flowchart showing the interrelationship of the financial management systems at the Food and Drug Administration. Appendix IV contains agency comments which were considered and appropriate changes were made in preparing this profile.

RESPONSIBILITIES OF THE FOOD AND DRUG ADMINISTRATION

Most of FDA's responsibilities (about 90 percent) are set by the Food, Drug, and Cosmetics Act (21 U.S.C. 301-392). This statute and its amendments require FDA to regulate the purity, quality, and content of foods (including food additives), color additives, human and animal drugs (including medicated animal feeds), medical devices, and cosmetics. FDA regulates products in interstate commerce as well as those imported. Meat and poultry are regulated by the U.S. Department of Agriculture under separate legislative authority.

FDA directly touches the day-to-day life of American citizens. Specifically, FDA is responsible for protecting the public health of the nation as it may be impaired by foods, drugs, biological products, cosmetics, medical devices, ionizing and nonionizing radiation-emitting products and substances, poisons, pesticides,

and food additives. FDA's regulatory functions are geared to insure that: foods are safe, pure, and wholesome; drugs, medical devices, and biological products are safe and effective; cosmetics are harmless; all of the above are honestly and informatively packaged; and that exposure to potentially injurious radiation is minimized.

The manufacturers have prime responsibility for ensuring that products are safe. FDA monitors manufacturers' activities to ensure that they are meeting their responsibilities for product safety. FDA sets, for example, requirements for manufacturing and laboratory practices as well as drug performance, identity, potency, and labeling standards. In addition, FDA examines product samples and inspects manufacturer facilities. If FDA discovers violations of the regulations and standards, it has the legal authority to require manufacturers to correct deficiencies.

FOOD AND DRUG ADMINISTRATION ORGANIZATIONAL STRUCTURE

The Food and Drug Administration consists of the Office of the Commissioner, five bureaus, regional, and district offices. The Commissioner of FDA reports to the Secretary for Health and Human Services and oversees the implementation of FDA programs. The five bureaus through the regional and district offices, direct day-to-day program operations. The Bureaus and field offices report to the Commissioner of FDA. A brief description of each organizational entity follows:

- --Bureau of Food regulates foods for human consumption and cosmetics--specifically all food in interstate commerce except for meat and poultry.
- --Bureau of Veterinary Medicine develops and conducts programs with respect to the safety and efficiency of veterinary preparations and devices; evaluates proposed use of veterinary preparations for animal safety; and evaluates FDA's surveillance and compliance programs relating to veterinary drugs and other veterinary medical matters.

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- --National Center for Drugs and Biologics regulates drugs manufacturing to help ensure that drugs for human consumption are safe, effective, and truthfully and informatively labelled. In addition, the Center approves new drugs for marketing on the basis of tests for safety and effectiveness of biologics (vaccines and toxins) which are made from living organisms and are used to treat, prevent, or diagnose disease.
- --National Center for Toxicological Research evaluates the safety of chemicals used in industry and the home. The Center receives funds from FDA and the Environmental Protection Agency. The Bureau's principal function is to develop better methods of conducting comprehensive toxicological evaluations of chemicals.

- of Medical Devices implements the 1976 medical device amendments to the Federal Food, Drug, and Cosmetics Act, which sets standards for medical devices to diagnose or treat disease or to affect the structure or a function of the body. Medical devices include artificial limbs, organs, and equipment such as sophisticated x-ray equipment. In addition, the Center is also responsible for implementing the Radiation Control and Health and Safety Act of 1968 which sets standards for radiation equipment. Radiation is either ionizing (x-rays) or nonionizing (microwaves, light waves and sound waves). The Bureau emphasizes and monitors research and development of improved procedures and training for health professionals to help reduce the risk of adverse side effects to patients undergoing radiological treatments.
- --Regional and district offices personnel conduct required inspections and investigations of food and drug manufacturers' facilities, perform laboratory tests on food and drug products, and recommend enforcement actions relating to violations of FDA standards and regulations. The work done by regional and district office personnel is overseen by the Executive Directors of Regional Operations. The regional and district offices employ about 3,000 people which is approximately 45 percent of FDA's total workforce.

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FINANCIAL MANAGEMENT STRUCTURE OF THE FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration operates and uses six automated financial management systems. These systems are briefly described below.

- --FDA Umbrella Accounting System maintains FDA's general ledger accounts, records the financial results of program and administrative operations, produces internal and external financial reports, and administratively controls FDA's spending authority.
- --Property Accountability Inventory System maintains detailed property accounts that support the financial control accounts in the Umbrella Accounting System. This system maintains the subsidiary ledger personal property accounts to support the summary property control accounts in the general ledger.
- --Certification Accounting System maintains detailed accounts including advances and charges for companies who submitted substances for testing under the FDA Insulin and Color Additives Certification Program. This system maintains the subsidiary accounts receivable ledger to support various control accounts in FDA's general ledger maintained by the Umbrella Accounting Systems.

These three systems, taken together, authorize payments, control assets and liabilities, record and control receipts, provide for administrative control of FDA's spending authority, and produce internal and external financial reports. We did not survey the operations of the Property Accountability Inventory System and the Certification Accounting System because of staff and time constraints.

The following FDA financial management systems, are operated at the bureaus and provide for the administrative control of spending authority. A brief description of each system follows:

- --Automated Ledger System is run by the Bureau of Foods to record and control the status of its spending authority. Bureau of Foods commitments are recorded in this system as well as in the FDA Umbrella Accounting System. Monthly, the Umbrella Accounting System's and this system's records are reconciled and adjusted accordingly.
- --Bureau integrated Tracking System is run by the National Center for Devices and Radiological Health Bureau of Medical Devices to record, report, and control obligations and expenditures for training, travel, supplies, equipment and contracts. Commitments are recorded in this system as well as the FDA Umbrella Accounting System. Information in this system is reconciled on a monthly basis with information in the Umbrella Accounting System and adjusted accordingly.
- --Financial Operating System is run by the Bureau of Veterinary Medicine to record, report and control commitments. Obligation and expenditure information is recorded in this system as well as the Umbrella Accounting System. Information in both systems are reconciled on a monthly basis and appropriate adjustments are made.

These systems duplicate the control functions served by the Umbrella Accounting System. FDA is aware of the problem and as discussed on page 11 efforts are underway to correct the situation.

In addition, we identified six systems that provide FDA managers with reports on the financial results of program and administrative operations that are used in the decision making process. These systems do not authorize payments, record and control assets and liabilities, record and control receipts, or administratively control spending authority. These six systems are the:

- -- Resource Use System.
- -- Automated Planning Tool System.
- -- Travel Voucher Control.
- -- Contracts and Grants Management Information System.

- --Administrative System.
- -- Personnel Training System.

We did not survey these six reporting systems because they were not considered part of FDA's financial management structure.

FDA'S UMBRELLA ACCOUNTING SYSTEM

The Umbrella Accounting System is FDA's primary financial management system. It administratively controls FDA's spending authority which amounted to \$378 million in fiscal 1982. FDA's Umbrella Accounting System receives information from and sends information to other Departmental systems. The system produces internal financial reports and all external financial reports required by Congress, OMB, and Treasury.

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System Overview

The Umbrella Accounting System operates on computer equipment in the Public Health Service's Parklawn Computer Center, Rockville, Maryland. The system interfaces with the Departmental Central Payroll System, Central Registry System, and Departmental Federal Assistance Financing System (DFAFS). It also receives information from and sends reports to FDA headquarters, district and field offices, which are considered accounting points and separate accounting entities. Information is received from and sent to the Departmental systems via magnetic tape and telecommunications. Information from FDA accounting points is received via computer terminal.

The Umbrella Accounting System maintains the general ledger and a series of automated files to record, report, and control financial information. The operations of the Umbrella Accounting System are briefly described below. Appendix II summarizes the system's internal control strengths and weaknesses and appendix III contains a flowchart of the system.

System inputs

Accounting transactions relating to each accounting point are recorded in the Umbrella Accounting System's automated files in ways to permit financial reporting by accounting point. Each accounting point enters its own transactions into the Umbrella Accounting System and requests the reports required by management.

Transactions to authorize the obligation and disbursement of funds are initiated by offices and are forwarded on fiscal documents such as purchase orders, travel vouchers, and requests for payment, to the accounting point for entry into the Umbrella Accounting System. At the accounting point the information on fiscal documents is transcribed to a special form—the Document History Record (DHR). Data recorded on the DHR is then entered into the Umbrella Accounting System by computer terminal. In addition, each accounting point prepares a manual Voucher and

Schedule of Payments (SF-1166) which is sent to the Treasury Regional Disbursing Office to initiate the actual preparation and issuance of checks for payment of such expenditures as vendor invoices and travel vouchers.

The Umbrella Accounting System receives inputs on a daily, bi-weekly, and monthly basis. Daily, information on contracts, procurements, travel, and other administrative obliqations and expenditures from accounting points is entered into the system via computer terminal. This information is processed at night. Bi-weekly, a magnetic tape is received from the Department's Central Payroll System which includes summary information on payroll expenditures and payroll costs for FDA employees. Monthly, data is received from the Departmental Federal Assistance Financing System (DFAFS) and the Central Registry System (CRS).

DFAFS is the Department-wide system that controls and records (1) cash advances to Letter-of-Credit holders of HHS contracts and grants and (2) expenditures of advanced funds reported by contractors and grantees. DFAFS provides a magnetic tape file of cash advances made to FDA contractors and grantees and expenditures reported by FDA contractors and grantees to the Umbrella Accounting System.

CRS is the Department-wide system that maintains an automated file of the name, identification number, and address of all organizations and individuals authorized to receive payments from HHS and/or to make payments to HHS. CRS provides a magnetic tape file of all organizations and individuals authorized to receive payments from and make payments to HHS to FDA's Umbrella Accounting System.

System Processing

Each night, the Umbrella Accounting System consolidates all transaction information received during the day into a single transaction file. This file will, on a daily basis, include all transaction information sent in from FDA's accounting points. Bi-weekly, the transaction file will include the information received from FDA's accounting points and the information received from the Central Payroll System. Monthly, the transaction file will include the information received from FDA's accounting points and the information received from the Central Payroll Systems, DFAFS, and CRS.

To control access to the Umbrella Accounting System and its files, the system uses passwords and transaction codes. Passwords identify individuals authorized to enter information into the system and screen-out unauthorized individuals who attempt to access the system and its files. Transaction codes limit the kinds of information that can be entered into the system to update general ledger accounts and detailed subsidiary automated files. For example, the Umbrella Accounting System, based on a particular transaction code, will ask/prompt the computer terminal operator for the required information. Overall, the Umbrella Accounting

System is designed to recognize about 125 transaction codes. Without entering a recognized transaction code into the system, the user will be unable to enter information into the system.

After the Umbrella Accounting System creates the transaction file, the information in the file is edited for completeness and accuracy. The Umbrella Accounting System performs numerous edit checks. These edit checks can be grouped into the following categories:

- --Alpha/numeric edits verify the reasonableness of information in a transaction. For example, an alpha/numeric edit would check to determine whether all characters in a purchase order number are numeric.
- --Relational edits test the accuracy of one item of information against a related item of information in the transaction. For example, a relational edit would check to determine if the effective date for a vendor authorization to deliver goods or perform services was within the current fiscal year.
- --Transaction versus Reference File edits check the accuracy of information in a transaction in relation to standard items of information recorded in automated reference files. The reference files are discussed in more detailed below.

The Umbrella Accounting System uses the following automated reference files to validate the information in transaction records:

- --Open Document File contains all the documents which are currently "open" in the system: i.e., those obligations and commitments for which final disbursement or other final action has not been made. This file shows each commitment which has not been fully obligated and each obligation which has not been fully disbursed.
- --Allotment/Allowance File maintains a running uncommited, unobligated balance for each allotment allowance. This file is used to validate the availability of funds for transactions posted to the Open Document File.
- --General Ledger Decode File specifies which general ledger codes are to be debited and/or credited for specific combinations of transaction code, object class, and federal and nonfederal codes.
- --Vendor File contains a record for each organization or individual doing business with FDA. Each entity is assigned a unique identification number. The Vendor File contains each entity's identification number, name, and address.
- --Miscellaneous Code Descriptor File contains a list of all valid codes used by the Umbrella Accounting System and description/explanation of the meaning of each code. This

file is used to edit and validate codes in transaction records, provide standard report headings, and control file updates.

-- Detail Transaction File contains all error-free transactions which have been processed through the system.

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- --Allotment Ledger File maintains allotment, commitment, obligation, and disbursement balances by object class for FDA organizational element and program.
- --General Ledger File maintains general ledger accounts by accounting point, appropriation and fiscal year.
- --Rotating Error File contains all transactions rejected by the computer. Rejected transactions are recorded in the Rotating Error File as originally entered into the Umbrella Accounting System. Rejected transactions are kept on the Rotating Error File until a corrected transaction is resubmitted for computer processing and passes computer edits. In some cases a rejected transaction will be deleted from the Rotating Error File when another related transaction is entered into the system. For example, a disbursement transaction processed before a related obligation will be rejected until the related obligation is processed.

Systems outputs

The Umbrella Accounting System produces a series of hardcopy reports. Approximately 50 reports are issued on a monthly basis. Each FDA accounting point requests the needed reports and distributes them to the management program and operating officials. The various reports produced by the Umbrella Accounting System are available on a daily, weekly, or monthly basis depending on the purpose of the individual reports. Daily reports may be requested on a "next day", or 24-hour basis. Weekly reports are available on request following end-of-the-week update. Monthly reports are available after the fifth work day of the month following the end of the reporting month.

In addition to the printed reports, the Umbrella Accounting System produces the following files for the following Departmental automated systems:

- --Central Registry Systems (CRS) receives from the Umbrella Accounting System a magnetic tape file of all individuals and organizations that FDA makes payments to and receive payments from. The information on this file includes the individual and organization name, identification number, and address.
- --Departmental Federal Assistance Financing System (DFAFS) receives from the Umbrella Accounting System a telecommunicated file of all awards of contracts and grants. This file includes the contractors' or grantees' name, identification

code, address, amount of the contract or grants, (the obligation amount) and period of time covered by the contract or grant.

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FDA Umbrella Accounting System internal control strengths and weaknesses

It appears that the internal controls of the FDA Umbrella Accounting System are adequate to ensure that the financial results of program and administrative operations are completely and accurately recorded and reported and that FDA's spending authority is not breached. The internal control strengths and weaknesses are summarized below.

The key internal control strengths in FDA's Umbrella Accounting System include:

- --Use of passwords and transaction codes to restrict access to the system and to limit and control the kinds of information that is entered into the system and files.
- --Extensive computer edit checks of transaction information entered into the system through the use of computer maintained reference files to ensure that transaction information is complete and accurate.
- --Automated control of a transaction rejected by computer edits to ensure that the transaction is corrected and reentered into the computer for processing in a timely manner.
- --Regularly scheduled internal audits and analysis made by the FDA Accounting Branch and periodic on-site reviews of FDA's accounting points.

We also noted certain internal control weaknesses in the Umbrella Accounting System. FDA is aware of these areas and their effort to correct the problems are discussed on page 11. The specific weaknesses we found are:

- --Information is not processed in the most efficient and economical manner,
- --Duplicate systems are operated by several FDA bureaus.
- -- The month-end Treasury report is prepared manually.

At the accounting points, information is transcribed from fiscal documents--purchase orders and travel orders, for example--onto a Document History Record prior to processing this information through the computer. This process increases the possibility of errors being entered into the computer. FDA could input transaction information directly from the fiscal documents into the system. In addition, when data is processed through the Umbrella Accounting System, accounting points are not advised of errors detected by the systems' extensive edit routines until the following day when error listings can be requested and received. However, prior to the transmission of data by the accounting points, some general edits are performed. Batches are also verified before transmission. If transactions were completely edited when they were being entered, the various accounting points could immediately correct any errors.

Currently the SF-224 report must be mailed by the third working day following the end-of-the month by each accounting point to the Treasury office that made disbursements for the individual accounting points. This report is manually prepared and is supported by manual records and reports produced by the Umbrella Accounting System. The system does not produce the final monthly financial reports until the fifth working day following the end of the reporting month.

In addition, we also found that a comprehensive review of the operation of the FDA Umbrella Accounting System has not been performed by either GAO or the HHS Inspector General. We realize routine audits and analysis are made by FDA's Accounting Branch, however, an independent in-depth evaluation should be performed to ascertain whether controls in the system are in fact operating as designed.

Also, several Bureaus have systems that in part duplicate the Umbrella Accounting System. The main purpose of the bureaus' systems is to provide day-to-day information on the status of their funds. Personnel in the bureaus indicated that the FDA accounting system provides data on the status of funds on a monthly basis which is not frequent enough for their management needs. According to bureau officials, a day-to-day status of funds is necessary to preclude the bureaus from exceeding their spending authority. Monthly, each bureau reconciles the status of funds per the FDA accounting system with that shown on their own system, investigates any differences, and makes the necessary adjustments to insure that the status of funds on both systems agree.

QUESTIONNAIRE RESULTS FOR THE ACCOUNTING AND ADP REPORT RECIPIENTS AT FDA

As part of our survey we sent a questionnaire to Headquarters and regional office recipients of accounting and ADP reports generated by the FDA Umbrella Accounting System. The questionnaire addressed three major issues: report usage, report accuracy and report timeliness. Of the 474 FDA respondents—190 headquarters and 284 regions—71 percent of the headquarters recipients and 94 percent of the regional office recipients reported that they use the reports. Whereas, 9 individuals or 3 percent, in headquarters and 8 individuals or 4 percent in the regions reported that they did not use the reports.

Of the 190 headquarters staff who receive the reports, 170 or 90 percent found the reports to be accurate and timely. In the region's 276 of the 284--97 percent--believed the financial reports were accurate and timely.

Overall, the accounting and ADP reports sent to FDA recipients appear to be useful, accurate and timely. However, a future study may be warranted to (1) review the mailing list used to distribute reports and (2) analyze the usefulness of individual reports.

FDA'S SYSTEM ENHANCEMENT EFFORTS

At the start of fiscal 1984 FDA has several efforts underway to enhance the capability of the FDA Umbrella Accounting System. These efforts, include:

- --Eliminating duplicate systems in the bureaus.
- -- Eliminating the Document History Record.
- -- Automating month-end Treasury reporting requirement.

The improvements to the Umbrella Accounting System are initially directed at the bureau level in order to eliminate the need for existing duplicate fund control systems. According to FDA officials, a pilot program with the Bureau of Food began in August 1983 to permit direct access to the FDA accounting system for input of fund commitment information. This system enhancement will eliminate the need for the Document History Record to be prepared each time a commmitment is made. The other FDA activities will be phased in on an individual basis throughout fiscal 1984 and 1985. This enhancement will also permit direct entry of disbursement information from hardcopy, such as the purchase order, into the Umbrella Accounting System. In addition, when the enhancement is completely implemented, it is anticipated that all error checking will be performed at the terminal prior to the transmission of any data.

FDA is also in the process of developing an automated SF-224 reporting system. The SF-224 report will be prepared and balanced at headquarters and in each district office using minicomputers. The reports will be collected by FDA's Division of Financial Management and transmitted to Treasury. The SF-224 reporting cycle will be identical to the accounting system cycle which should reduce errors due to transcribing amounts from printouts to the SF-224-as is now the case.

APPENDIX I

OBJECTIVES, SCOPE, AND METHODOLOGY

This survey viewed the Food and Drug Administration as a financial entity and focused on identifying its financial management structure, related systems, and internal control strengths and weaknesses in the structure. The survey applied GAO's Controls and Risks Evaluation (CARE) audit approach.

SURVEY OBJECTIVES

Our survey objectives were to (1) document all manual and automated systems at the Food and Drug Administration that process financial transactions from the time they are authorized through final reporting of these transactions in internal and external reports, (2) identify the relationships between these systems, that is, the flow of information among different systems, and (3) identify and document internal control strengths and weaknesses in the systems.

SURVEY SCOPE

This survey viewed the Food and Drug Administration as a single financial entity. Therefore, we identified and surveyed the financial management systems in the various organizational components of the Administration. Survey work was performed at the Headquarters of the Food and Drug Administration, Rockville, Maryland; and the Atlanta, Georgia; Baltimore, Maryland; and Philadephia, Pennsylvania regional offices.

We documented the financial management systems in operation and identified, based on available system documentation and through discussions with agency accounting, program officials, and review of prior GAO, Inspector General and special system study group reports, the internal control strengths and weaknesses in these systems. We did not perform any tests of system operations or actual financial information and transactions. The following sections present the definitions of a financial management system, internal control, and an agency system of internal control used in this survey.

DEFINITION OF A FINANCIAL MANAGEMENT SYSTEM

In consonance with GAO's Policy and Procedures Manual for Guidance for Federal agencies (Titles 2 through 8), we defined a financial management system for this survey, as the manual and/or automated systems that capture, record, summarize, and/or report financial and related quantitative information related to the:

- -- Authorization of the use of resources.
- -- Management of liabilities.
- -- Receipt of revenue.

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- --Disbursement of funds.
- --Control of assets.
- -- Control of appropriated funds.
- --Development and issuance of reports on the financial status of assets, liabilities, and appropriated funds and the financial results of program and administrative operations.

In our April 18, 1983, letter to the heads of Departments and agencies, the Comptroller General announced changes to GAO's procedures for approving agency accounting systems. In this letter, the Comptroller General reiterated the definition of an accounting systems in GAO's Policy and Procedures Manual for Guidance of Federal Agencies.

DEFINITION OF INTERNAL CONTROLS

On June 16, 1983, the Comptroller General issued the standards for internal controls in the federal government to be followed by agencies in establishing and maintaining systems of internal controls. The standards define systems of internal controls as

"The plan of organization and methods and procedures adopted by management to ensure that resource use is consistent with laws, regulations, and policies; that resources are safeguarded against waste, loss, and misuse; and that reliable data are obtained, maintained, and fairly disclosed in reports."

Processing procedures are those manual and/or automated procedures that govern capturing, recording, processing, summarizing, and reporting of financial and related quantitative information. Internal control procedures and independent procedures provide evidence that processing procedures have, in fact, been followed.

DEFINITION OF AN AGENCY'S SYSTEM OF INTERNAL CONTROL

Most agencies operate several financial management systems that provide information to each other. The individual financial management systems—taken together—form the agency's overall financial, accounting, control, and reporting system. For example, most agencies have a general ledger/administrative control of funds system, and subsidiary systems that process transactions relating to personnel/payroll, personal property, disbursements, receipts, loans, accounts receivable, and accounts payable. These systems—taken together—are the agency's overall financial, accounting, control, and reporting system.

The financial management systems that make up an agency's financial management structure include both processing procedures and independent internal control procedures, as defined in the preceding two sections. For this survey, we defined an agency's

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system of internal control as all the internal control procedures—taken together—that are included in all the financial management systems that comprise the overall financial, accounting, control, and reporting system.

FOOD AND DRUG ADMINISTRATION FINANCIAL MANAGEMENT SYSTEMS INCLUDED IN OUR SURVEY

Based on the foregoing definitions, we included in our survey all manual and automated systems at the Food and Drug Administration that:

- --Maintain general ledger accounts and produce financial reports.
- --Control appropriated funds.
- --Validate information from subsidiary financial management systems that feed information to general ledger systems.
- --Determine eligibility for, and authorize the making of payments to vendors.
- -- Authorize acquisition of resources.
- -- Record and account for assets and liabilities.

SURVEY METHODOLOGY

Our survey work followed the requirements of GAO's Controls and Risk Evaluation (CARE) audit approach. Accordingly, our survey included identification and documentation of the Administration's:

- --Organizational structure and major organizational components and the mission of each component.
- --Accounting and related financial management systems, as previously discussed, and the interrelationships between these systems.
- --Internal control strengths and weaknesses in the Administration's systems based on the internal control strengths and weaknesses identified during the survey.

In consonance with the CARE audit approach our work entailed identification and documentation of the operations and related internal control strengths and weaknesses of the Administration's financial management system based on (1) available agency system documentation, (2) discussions with cognizant agency accounting, program, and ADP officials, and (3) prior GAO, Inspector General, and special study group reports. Our survey was made in accordance with our current "Standards for Audit of Governmental Organizations, Programs, Activities, and Functions," except, tests were not performed of system operations or of information processed by

Control Weaknesses

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM ASSET AND LIABILITY MANAGEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEARNESSES

Cycle Control Objectives

Controls in Place

Authorization

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- 1. Sources of assets and liabilities should be authorized in accordance with laws, regulations and management's policy.
- 2. The amounts, timing and conditions of transactions should be authorized in accordance with laws, regulations and management's policy.
- 3. The amounts, timing and conditions of expenditures of funds should be authorized in accordance with laws. regulations and management's policy.

4. Adjustments to assets and liabilities accounts and account distributions should be authorized in accordance with management's policy.

The automated FDA Umbrella Accounting System includes a vendor masterfile which lists all vendors authorized to enter into agreements with FDA organizational components. The vendor masterfile is maintained by FDA Headquarters and specific procedures are in place to add or delete a vendor. All purchase orders are matched against the vendor file. If the vendor on the purchase order does not match the vendor file the purchase order is rejected from further processing.

The requestor for goods and services prepares a requisition which is submitted to the purchasing agent. The purchase order is then prepared which must include a valid common accounting number (CAN), object class and appropriation citation. During the edit cycle, if this information is found to be in error, an error message is printed out.

When items have been received and the appropriate entries are made on the Document History Record (DHR), the data is transmitted to the FDA Umbrella Accounting System. The entries on the DHR record will show the actual amount of the purchase. In essence, this entry commits the amount of the estimated commitment, and obligates the actual purchase amount. The Fiscal Office, at the same time, prepares the documentation necessary for the payment of the vendor's invoice by Treasury. After Treasury has made payment and FDA is notified, the Fiscal Office records on the DHR the amount of the payment, whether it is in full or a partial payment, and then submits data for processing by the accounting system.

See cycle control objective 3.

APPENDIX

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FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM ASSET AND LIABILITY MANAGEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Controls in Place

Cycle Control Objectives

procedures should be established and maintained in accordance with

See cycle control objectives 1, 2, and 3,

Economy, Efficiency and Effectiveness

5. Asset and liability management

management's policy.

6. Cycle results should be in accordance with laws, regulations and management's policy and plans.

7. Cycle results should be achieved in an economical and efficient manner.

The FDA Umbrella Accounting System is an automated double-entry accural accounting system, using the uniform chart of general

ledger accounts. In addition, the FDA Accounting Manual is issued to all FDA's Accounting Points and to FDA Program Managers.

The FDA Umbrella Accounting System issues various reports monthly and yearly on the status of funds and general ledger account balances. Also, the Treasury SF-224 report is prepared monthly on the third working day of the month, following the end of the month.

See cycle control objectives 1, 2, 3, and 6.

Because of the lack of edits when data is entered by terminal from the Document History Record (DHR), user is not aware of all errors until the day following submission of data. Consequently. incorrect data is entered into the transaction file, and remains until the originator has made the appropriate corrections. The system provides that entries that relate to a particular month cannot be made until the fifth or sixth of the following month. As a result, the Treasury SF-224 Report must be prepared manually because it must be sent by the third working day following the end of the month.

Control Weaknesses

See cycle control objective 7.

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM ASSET AND LIABILITY MANAGEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle Control Objectives

Processing procedures used to create, recognize and report events and related transactions should be economical and efficient.

Transaction Processing

- Only those requests to buy or sell assets that meet laws, regulations and management's policy should be approved.
- Assets and liabilities acquired should be accurately and promptly reported.
- Retirements or dispositions of assets to outsiders should be accurately and promptly reported.
- 12. Amounts due from or to purchasers and creditors, and the accounting distribution of those amounts, should be computed accurately and promptly recognized as assets or liabilities.
- Changes in values should, where required by generally accepted governmental accounting principles, be computed accurately and recognized promptly.

Controls in Place

See cycle control objectives 1, 2, 3, and 6.

See cycle control objectives 1 and 2. Also, within the Property Accountability Inventory System procedures are outlined on the sell, transfer, exchange and/or disposal of assets.

See cycle control objectives 3 and 6.

See cycle control objective 6.

See cycle control objectives 3, 6, and 9.

See cycle control objectives 3, 6, and 9.

See cycle control objectives 3, 6, and 9.

Control Weaknesses

POOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM ASSET AND LIABILITY MANAGEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Control Weaknesses Controls in Place Cycle Control Objectives

Classification

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- 14. Amounts due to creditors, and related adjustments, should be accurately and promptly classified, summarized and reported.
- 15. Purchases and sales of assets, changes in liabilities and related adjustments should be accurately applied to the proper subsidiary accounts.
- 16. Journal entries for assets and liabilities acquired and retired, and related adjustments, should be prepared and posted each accounting period.
- 17. Journal entries should summarize and classify economic activities in accordance with management's plan.

See cycle control objectives 3, 6, and 9.

Substantiation and Evaluation

18. Recorded balances of asset and liability accounts, and related transaction activity, should be periodically substantiated and evaluated.

See cycle control objectives 3, 6, and 9. In addition, within the Property Accountability Inventory System, the procedures provide for an annual inventory and reconciliation of the property and accounting records.

coverage.

Lack of recent comprehensive audit

APPENDIX II

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM REPORTING CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle Control Objectives

Authorization

- Data entered to reporting systems should be authorized in accordance with laws, regulations and management's policy.
- Reporting system processing procedures should be established and maintained in accordance with laws, regulations and management's policy.

Economy, Efficiency and Effectiveness

- Reporting should be in accordance with laws, regulations and management's policy and plans.
- Reporting should be achieved in an economical and efficient manner.

Reporting procedures used should be economical and efficient.

Controls in Place

The FDA Umbrella Accounting System is an automated general ledger accrual accounting system, using FDA's uniform chart of general ledger accounts. In addition, the FDA Accounting Manual is issued to all FDA's Accounting Points and to FDA Program Managers.

The FDA Umbrella Accounting System issues various reports monthly and yearly on the status of funds and general ledger account balance. Also, the Treasury SF-224 report is prepared monthly on the third working day of the month, following the end of the month.

See cycle control objective 2.

Because of the lack of edits when data is entered by terminal from the Document History Record, the user is not aware of all errors until the day following submission of data. Consequently, incorrect data is entered into the transaction file and remains there until the user has made the appropriate corrections.

Control Weaknesses

See cycle control objective 4.

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM REPORTING CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

	Cycle Control Objectives	Controls in Place	Control Weaknesses
Tra	insaction Processing		
6.	Only those reports that meet management's policy should be approved,	See cycle control objective 2.	
7.	Reports should be prepared accurately and promptly.	Internal system edits such as the rotating error file and miscellaneous code descriptor file (MCDF) are used to edit accounting transactions as they are input into the system. If the transaction does not agree with the MCDF, it is rejected by the system and is printed out on an error listing.	
8. 20	Relevant disclosure data should be gathered accurately and promptly.	See cycle control objectives 2 and 7.	The system provides that entries that relate to a particular month cannot be made until the fifth or sixth of the following month. As a result, the Treasury SF-224 Report must be prepared manually because it must be sent by the third working day following the end of the month.
9.	Relevant disclosure data should be accurately summarized and reported.	See cycle control objectives 2 and 7.	
10.	File and account balances should be accurately and promptly reported.	See cycle control objectives 1, 2, and 7.	
11.	Consolidation of reports should be accomplished accurately and promptly.	See cycle control objectives 1, 2, and 7.	

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM REPORTING CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle Control Objectives

- 12. Reporting entries should classify activities in accordance with management's plan.
- 13. Reports should be prepared accurately and promptly, be prepared on consistent bases and fairly present the information they purport to display.

Substantiation and Evaluation

14. Recorded balances in the records should be periodically substantiated and evaluated.

Controls in Place

See cycle control objectives 1 and 2.

See cycle control objectives 1, 2, and 7.

Lack of comprehensive systems audit of the FDA Umbrella Accounting System by a independent party.

Control Weaknesses

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM OTHER DISBURSEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle Control Objectives

Controls in Place

The automated FDA Umbrella Accounting System includes a vendor

masterfile which lists all vendors which are authorized to enter

not on file a transaction cannot be processed to make a payment. Specific procedures are in place to add a vendor to the masterfile. When items have been received and the appropriate entries are made

on the Document History Record the data is transmitted to the FDA

into agreements with a FDA organizational component. If a vendor is

Control Weaknesses

Authorization

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- 1. Disbursements should be authorized in accordance with laws, regulations and management's policy.
- 2. Adjustments to disbursements and account distributions should be authorized in accordance with laws. regulations and management's policy.

3. Disbursement processing procedures should be established and maintained in accordance with laws, regulations and management's policy.

Economy, Efficiency and Effectiveness

4. Disbursement cycle results should be in accordance with laws, regulations and management's policy and plans.

Umbrella Accounting System. The entries on the DHR record will show the actual amount of the purchase. In essence, this entry commits the amount of the estimated commitment, and obligates the actual purchase amount. The Fiscal Office, at the same time, prepares the documentation necessary for the payment of the vendors invoice by Treasury. After Treasury has made payment and FDA is notified, the Fiscal Office records on the DHR the amount of the payment, whether

it is in full or a partial payment, and then submits data for processing by the accounting system.

This cycle control objective was not included in our survey.

procedures are in place to assure that disbursements are authorized for only goods and services received. Prior to authorizing payment by Treasury, all receiving reports, invoices, and purchase orders are compared to ensure that the goods and services ordered have been received.

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM OTHER DISBURSEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle Control Objectives

Disbursements should be made in an economical and efficient manner.

 Disbursement processing procedures used to create, recognize and report events and related transactions should be economical and efficient.

Transaction Processing

- Only those requests for disbursements that meet management's policy should be approved.
- Disbursements should be accurately and promptly reported,
- Amounts due to vendors for goods and services accepted, and the accounting distributions of such amounts, should be computed and recognized as liabilities promptly.

Controls in Place

See cycle control objective 1.

Monthly reports are prepared by the system showing the status of funds, and general ledger account balance. In addition, each organizational component must complete Treasury report SF-224 by the third working day following the end of the month. Also, see cycle control objective 2.

See cycle control objective 2.

Control Weaknesses

Because of the lack of edits when data is entered from the Document History Record, users are unaware that errors have been made until the day following submission of data. Consequently, incorrect data is entered into the transaction file and remains until the originator has made the appropriate corrections.

See cycle control objective 5.

Control Weaknesses

POOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM OTHER DISBURSEMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle control Objectives	Controls in Place
 Each disbursement of cash should be based upon a recognized liability, be accurately prepared and be appropriately authorized. 	See cycle control objective 2.
 Disbursements should be accurately and promptly classified, summarized and reported. 	See cycle control objectives 2 and 8.
 Cash disbursements and related adjustments should be accurately and promptly classified, summarized and reported. 	See cycle control objectives 2 and 8.
13. Liabilities incurred, cash disbursements and related adjust- ments should be accurately applied to the proper vendor's accounts.	See cycle control objectives 2 and 8.
Classification	
14. Transactions for amounts due to vendors, cash disbursements and related adjustments should be prepared each period.	See cycle control objective 8.
 Disbursements should be summarized and classified in accordance with management's plan. 	See cycle control objectives 2 and 8.
 Recorded balances of disbursements, and related transaction activity, 	See cycle control objectives 2 and 8.

should be periodically substantiated

and evaluated.

FOOD AND DRIG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM PROCUREMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle control Objectives

Controls in Place

Control Weaknesses

Authorization

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- Vendors should be authorized in accordance with laws, regulations and management's policy.
- The types, estimated quantities, and prices and terms of goods and services needed should be authorized in accordance with laws, regulations and management's policy.
- Adjustments should be authorized in accordance with laws, regulations and management's policy.
- Procurement cycle processing procedures should be established and maintained in accordance with laws, regulations and management's policy.

The FDA Umbrella Accounting System documentation shows a vendor masterfile which lists all vendors authorized to enter into agreements with FDA organizational components. The vendor masterfile is maintained by FDA Headquarters and specific procedures are in place to add or delete a vendor. All purchase orders are matched against the vendor file. If a vendor on the purchase order does not match the vendor file, the purchase order is rejected from further processing.

The requestor for goods and services prepares a requisition which is submitted to the purchasing agent. The purchase order is then prepared which must include an approved vendor, (See control objective 1), a valid common accounting number (CAN), object class and appropriation citation. During the edit cycle, if this information is found to be in error, an error message will be sent to the originator for correction.

Receiving report, invoice, and purchase order are compared when chipment is received. If items are broken, or if partial shipment is received, this data is annotated. Documentation is forwarded to Fiscal Office who makes appropriate entries on the Document History Record for processing to PDA accounting system. This Fiscal Office also prepares documentation for payment of bill by Treasury.

This particular cycle control objective was not included in our survey.

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM PROCUREMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle control Objectives

Controls in Place

Control Weaknesses

Economy, Efficiency and Effectiveness

- 5. Procurement cycle operations should be in accordance with laws, regulations and management's policy and plans.
- 6. Procurements should be achieved in an economical and efficient manner.

See cycle control objective 4.

7. Procurement procedures used should be economical and efficient.

See cycle control objective 6.

Transaction Processing

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- 8. Only those requests of vendors for goods or services that meet management's criteria should be approved.
- Only requested goods and services. should be accepted.

See cycle control objectives 1, 2 and 3.

See cycle control objective 3.

Because of the lack of edits when data is entered by terminal from the Document History Record, user is not aware of all errors until the day following submission of data. Consequently, incorrect data is entered into the transaction file and remains until the originator has made the appropriate corrections.

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM PROCUREMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle control Objectives

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Controls in Place

Control Weaknesses

10. Goods and services accepted should be accurately and promptly reported. When items have been received and the appropriate entries are made on the Document History Record the data is transmitted to the FDA Imbrella Accounting System. The entries on the DHR record will show the actual amount of the purchase. In essence, the entry commits the amount of the estimated commitment, and obligates the actual purchase amount. The Fiscal Office, at the same time, prepares the documentation necessary for the payment of the vendors invoice by Treasury. After Treasury has made payment and FDA is notified, the Fiscal Office records on the DHR the amount of the payment, whether it is in full or a partial payment, and then submit data for processing by the accounting system.

11. Amounts due to vendors for goods and services accepted, and the accounting distributions of such amounts, should be computed and recognized as liabilities promptly.

See cycle control objective 10.

12. Amounts due to vendors should be accurately and promptly classified, summarized and reported.

See cycle control objective 10.

13. Purchasing ad, stments should be accurately and promptly classified. summarized and reported.

See cycle control objective 10.

14. Liabilities incurred, and related adjustments, should be accurately applied to the proper vendors' accounts.

See cycle control objective 10.

APPENDIX

FOOD AND DRUG ADMINISTRATION'S UMBRELLA ACCOUNTING SYSTEM PROCUREMENT CYCLE INTERNAL CONTROL STRENGTHS AND WEAKNESSES

Cycle control Objectives

period.

- 15. Journal entries for amounts due to vendors and related adjustments should be prepared each accounting
- 16. Purchasing journal entries should summarize and classify economic activities in accordance with management's plan.

Substantiation and Evaluation

17. Recorded balances of accounts payable, and related transaction activity, should be periodically substantiated and evaluated.

Controls in Place

See cycle control objective 10.

See cycle control objective 10.

Lack of recent comprehensive audit coverage of the FDA Umbrella Accounting System.

Control Weaknesses

APPENDIX IV APPPENDIX IV

FOOD AND DRUG ADMINISTRATION'S COMMENTS ON PROFILE OF "THE FOOD AND DRUG ADMINISTRATION-ITS RESPONSIBILITIES, ACTIVITIES, AND FINANCIAL MANAGEMENT STRUCTURE"

1. Page 15^{1}

Internal Control Strenghts

No mention was made of the regularly scheduled internal audits and analysis made by the Accounting Branch, nor of the on-site reviews conducted of accounting points. These are integral parts of our internal control program and warrant mention in the report.

GAO NOTF: Profile has been changed to reflect above comment. See page 10.

2. Page 15, 16, 17¹ Weaknesses

Two of the weaknesses outlined, the Α. transcribing information onto a Document History Record (DHR) prior to processing, and the duplication of systems maintained by the bureaus, are items we are in the process of rectifying. fact, the Audit Report acknowledges our enhancement efforts in these areas on page 17 in a separate paragraph. feel, however, that a fairer picture of our situation as it exists could be presented by consolidating the documentation of the weaknesses and our corrective actions into a single paragraph.

CAO NOTE: Profile changed. See pages 9 and 11.

B. On page 16 it states that accounting points are not advised of errors until the following day when error listings can be requested, rather than at the point of entry.

It is not quite true that there is no editing done at the terminals. A number of general edits and required field edits are currently performed at the

¹ Page numbers refer to the draft profile and may not correspond to the page number in the final profile.

terminals. Batches are also verified before transmission. With the enhanced capability of the VAX we are incorporating as much error checking as possible at the time the record is entered. When we eventually have an on-line system all error checking will be performed at the terminal.

- GAO NOTF: Profile has been changed to reflect above comments. See pages 7 and 11.
- C. On page 16 it is noted that the SF-224 Report to Treasury is manually prepared and is supported by manual records and reports because the system does not produce final monthly financial reports until the fifth working day of the following month.

We are currently working on an FDA-wide SF-224 Reporting System. SF-224's will be prepared and balanced at head-quarters and in each district office using their minicomputers.

SF-224's will then be collected via DECNET on DFM's central VAX and transmitted in bulk to Treasury. The SF-224 cycle will exactly match the Accounting System Cycle and each system will be balanced against the other. There will be less errors due to transcribing figures from printouts to old SF-224 forms. Figures already in balance will be transmitted directly to Treasury.

- GAO NOTE: The profile enhancement section--page 11--discusses this effort.
- D. On page 16 it is noted that a comprehensive review of the operation of the FDA Umbrella Accounting System has not been performed by either GAO or the HHS Inspector General. Also the attachment to the report states in several instances "lacks internal and external audit."

We have had numerous external audits conducted on various segments of our financial operation by both of these APPENDIX IV APPPENDIX IV

offices, including a GAO audit during 1978. Also, we believe that the frequent notation "lacks internal and external audit" is over stated, since FDA has substantial internal audit procedures and there have been external audits as noted above.

GAO NOTE: The points refer to an independent evaluation and not FDA continual in-house effort.

3. Page 171

System Enhancement Efforts

It is noted that effective October 1983, all Bureaus will have direct access to the FDA Accounting System for input of fund commitment information.

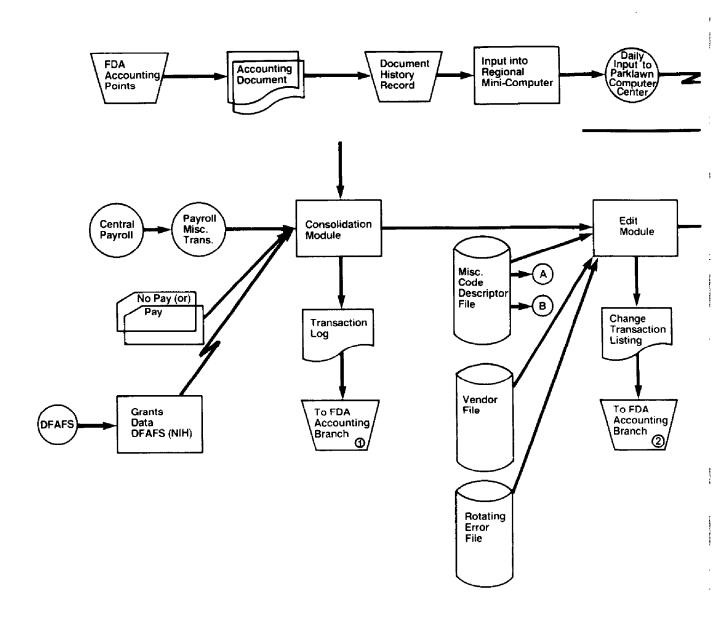
GAO NOTE: Profile has been changed to reflect above comments. See page 11.

That timeframe is not accurate. We will begin a pilot program with the Bureau of Foods in August 1983, and will thereafter begin to phase in other organizations on an individual basis through FY-84 and FY-85.

The profile has been changed to reflect the current implementation date. See page 11.

¹ Page numbers refer to the draft profile and may not correspond to the page number in the final profile.

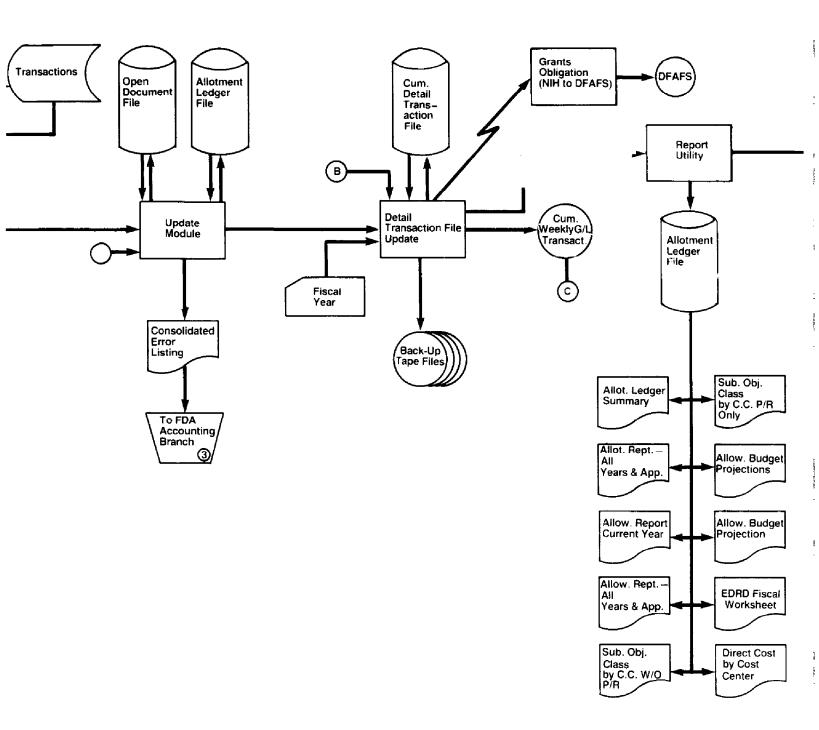
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- The Transaction Log is used to keep track of the number of transactions processed. This is a safety feature in case of computer processing interruption.
- The Change Transaction Listing is designed to keep track of changes made to records in the rotating error file. Besides keeping track of changes to the error file, this record keeps track of the number of cycles errors are processed without correction. This feature acts as a flag for management to highlight errors that have not been corrected.
- The Consolidated Error Listing contains each erroneous record in the rotating error file. This report is used by the Accounting Branch to review processing errors.

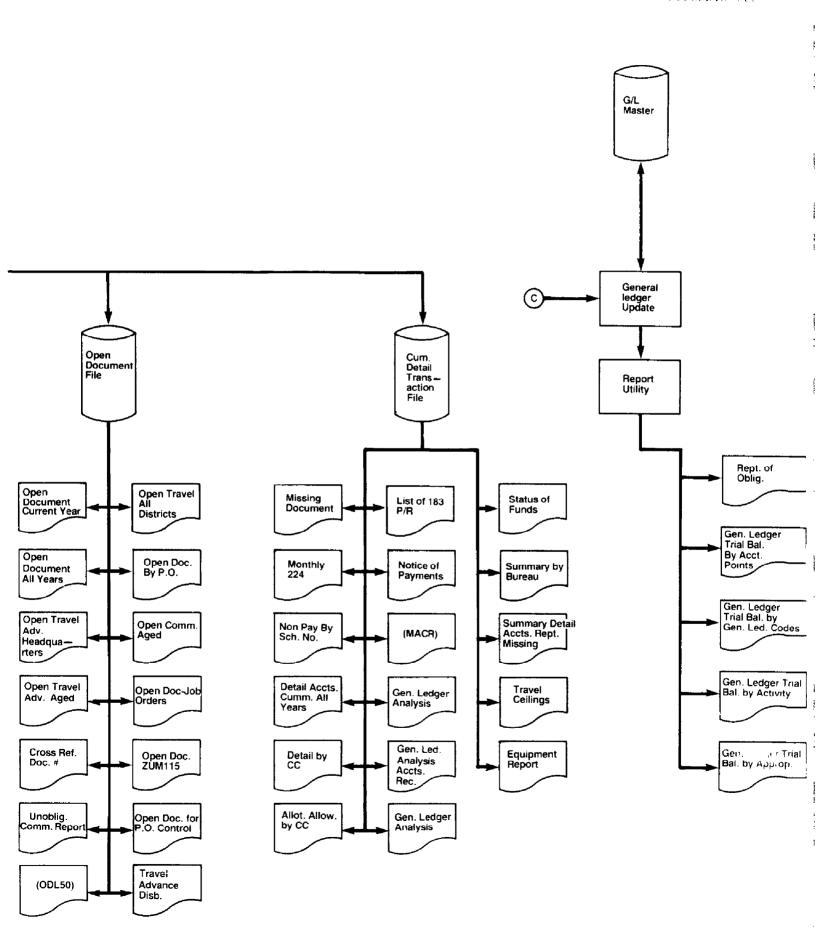
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Food and Drug Administration Financial Management Structure



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