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ADP PLANNING

FDA's Plans to Improve Processing of Medical Device and Drug Applications

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Information Management and
Technology Division

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The Honorable Quentin N. Burdick
Chairman, Subcommittee on Agriculture,
Rural Development, and Related Agencies,
Committee on Appropriations
United States Senate

The Honorable Edward M. Kennedy
Chairman, Committee on Labor and
Human Resources
United States Senate

The Honorable Thad Cochran
Ranking Minority Member, Subcommittee on Agriculture,
Rural Development, and Related Agencies,
Committee on Appropriations
United States Senate

The Honorable Orrin G. Hatch
Ranking Minority Member, Committee on Labor and
Human Resources
United States Senate

This report responds to your request, which asked us to review the Food and Drug Administration's (FDA) ability to adequately meet the growing demand for more timely processing of medical device and drug applications. In responding to your concerns we agreed, in a January 23, 1989, meeting with your offices, to (1) report on the existence of any automated data processing (ADP) plan that FDA has developed to improve the processing of medical device and drug applications, (2) review the plan to determine if it meets Health and Human Services (HHS) requirements for developing an automated system, and (3) provide any cost estimates for carrying out the plan.

Also, we agreed that, if we found that FDA does not have such an ADP plan, we would provide general guidance on what this plan should include.

Responsibility for reviewing and approving medical device and drug applications is divided between two centers within FDA. The Center for

Devices and Radiological Health, which reviews medical device applic tions, has prepared an ADP system plan to improve the quality and tim liness of its application reviews. The Center's plan follows HHS system development requirements, for the most part. The Center estimates th carrying out its plan will cost $3 million through fiscal year 1993.

The Center for Drug Evaluation and Research, which reviews drug applications, has not prepared a plan. This Center is, however, partici pating in several activities aimed at improving its drug-review proces and Center officials state that they are now in the process of developi a plan. As agreed, we have included as appendix I general guidance fc developing an ADP system plan.

Background

The FDA is one of seven agencies that make up the Public Health Servi branch of the Department of Health and Human Services. FDA is made of six centers, two of which, the Center for Devices and Radiological Health and the Center for Drug Evaluation and Research, are discusse in this report. As part of its mission, FDA is responsible for assuring co sumers that medical devices and drugs are safe and effective for thei intended uses. To determine this, the agency reviews applications seel ing FDA's approval to market medical devices and drugs.

FDA's principal automated data processing/telecommunications organi tion is its Division of Information Resources Management, within the Office of Management and Operations. The Division of Information Resources Management is responsible for agency-level ADP, office aut mation, telecommunications, security, acquisition approvals, planning and budgeting, and technical support for the staff offices of the FDA Commissioner.

The Division of Information Resources Management requires each FDA center, FDA's Office of Regulatory Affairs, and the Office of the Comm sioner to (1) annually submit a 5-year information resources manage- ment strategic plan, and (2) usually follow a system development life- cycle[1] methodology. The division accepts or rejects centers' 5-year pla based on such factors as available funding and the extent to which th plans support FDA's overall mission. Subsequently, the Division of Inf mation Resources Management prepares a consolidated, agency-wide

[1]A system development life-cycle methodology divides the automated system development proce into distinct phases and allows periodic management review. Federal Information Processing Sta dards Publications 64 and 38 divide the process into 3 phases: initiation, development, and opera

information resources management strategic plan, which the agency includes in its overall budget submission to the Department of Health and Human Services. While the division oversees the agency's larger, strategic plan for information resources, it does not oversee the details of system development planning for individual, center-level systems.

FDA has delegated responsibility for system development planning for the processing of medical device and drug applications to the two centers responsible for reviewing medical device and drug applications: the Center for Devices and Radiological Health and the Center for Drug Evaluation and Research. Each center has an information resources management staff, which is responsible for preparing its own ADP system plans.

The Health and Human Services' Information Resources Management Manual states that all automated information systems being developed and operated under its sponsorship, whether new or undergoing extensive modification, shall apply the life-cycle management concept to the planning, development, and operation of automated information systems. This concept calls for the preparation of specific planning documentation. See appendix I for further details.

Automated Data System Plans for Processing Medical Device and Drug Applications

Medical Device Applications

The Center for Devices and Radiological Health, as a scientific and regulatory organization within FDA, receives and reviews medical device applications relating to the safety and effectiveness of medical devices and radiation-emitting products. These applications include requests for approval to either bring a product to market or to develop a set of rules to investigate the safety and effectiveness of a device. In 1988, the Center acted on 9,900 applications, which involved reviewing approximately 810,000 pages of documentation.

In addition to the large volume of application documents originating outside FDA, Center personnel generate a large volume of documents in reviewing, evaluating, monitoring, and developing policy for regulated products. The Center faces significant problems in physically handling and storing these documents and in making them available, in a timely manner, to reviewers and regulators who must have access to data contained in the documents.

In response to the above problems, in November 1988, the Center prepared an ADP system plan, setting up a strategy for acquiring and using optical disk document image processing.[2]

The Center selected this technology after considering alternatives and conducting a number of pilot tests and evaluations of a prototype system. The Center concluded that, not only would this technology alleviate its paperwork storage problems, it would also improve the timeliness of its application review process by

- allowing several reviewers to access the same application documents at the same time;
- eliminating the need to transport paper documents between reviewers located at dispersed Center locations; and
- eliminating delays associated with lost or misplaced documents, since the original documents are permanently stored on optical disks, and reviewers may retrieve the document images when needed.

In its 1988 automated data processing system plan and related documents, the Center satisfied most of the initiation-phase elements that need to be addressed under federal system development guidelines. Its documentation included

- information on such activities as feasibility studies, cost/benefit analyses, and risk analyses;
- alternative ways to carry out the plan;
- the effect of the plan on the Center's human resource needs;
- project milestone dates; and
- cost estimates.

[2]Optical disk document image processing uses laser technology to capture images of documents, store these images on laser disks, and allow users to retrieve and view photograph-like images of stored documents.

The Center's planning documents, however, did not address a methodology for measuring and monitoring system performance. Although the Center has not prepared formal documentation concerning this planning element, the Center has developed a methodology for evaluating performance. According to the Center's information systems director, the methodology involves (1) using an existing automated system, which tracks the amount of time it takes the Center to process an application; and (2) administering a questionnaire to users of the new system. By using this methodology, the Center expects to determine whether the new system improves the quality and timeliness of the review process.

In March 1989, the Center submitted an agency procurement request for optical disk document image processing equipment to the Director of Information Resources Management, Office of Management and Operations. The Center plans to complete acquiring, installing, and evaluating the new technology by September 1991, and estimates that carrying out the plan will cost $3 million from fiscal years 1989 through 1993.

Drug Applications

The Center for Drug Evaluation and Research reviews, analyzes, and approves or disapproves drug firms' applications to market drugs for human use. In 1988, the Center acted on 1,541 applications, which involved reviewing approximately 7.6 million pages[3] of documentation.

Although Center officials recognize the need to improve management of the Center's review and approval process, they acknowledge that they have not prepared an overall automation plan to improve the quality and timeliness of drug application reviews. Center officials state, however, that they are now in the process of developing a plan. According to these officials, the Center's current 5-year information resources management strategic plan is the only document it has that can be considered a current planning document. This 5-year plan includes ongoing and planned activities aimed at improving its drug-review process.

One ongoing activity has been to integrate many of the Center's independent, software applications by modifying them to use the Center's data base management system, called the Center-wide ORACLE Management Information System (COMIS). This effort, which began several years ago, is intended to allow easier access to review data, which will improve

[3]These figures exclude the applications received for one category of application, the abbreviated new drug application. For this application category, we only received fiscal year, rather than calendar year statistics.

support to management, reviewers, and other personnel involved in the drug application review process. The Center reported costs, pertaining to its COMIS effort, of $1.8 million for fiscal years 1986 through 1988. The Center estimates that continuing to enhance and maintain COMIS will cost an additional $4.2 million from fiscal years 1989 through 1995.

Also, over the past 3 years, the Center, working with the Pharmaceutical Manufacturers Association, has supported pilot tests involving drug firms submitting applications electronically, to determine whether electronic submission of application data results in more efficient reviews. In 1988, the Center played a key role in FDA developing and publishing guidelines for drug firms to use to submit drug applications electronically.

Center officials also mentioned four activities aimed at improving its drug-review process. First, in 1987, the Center revised regulations to allow drug firms a greater role in the drug review and approval process and to simplify the application format. Second, the Center prompted a 1989 survey of drug firms to help it forecast and plan for the volume of applications the firms will need to have reviewed over the next 3 years. Third, the Center is currently supporting the creation of a non-profit corporation aimed at training professionals to help FDA carry out drug evaluations and education and research projects. Finally, the Center is proposing to pilot test optical disk document image processing in one of its divisions.

Scope and Methodology

We conducted our survey at FDA headquarters and FDA's Centers for Devices and Radiological Health, and Drug Evaluation and Research in Rockville, Maryland. To evaluate FDA plans to expedite the processing of medical device and drug applications and to determine the costs associated with carrying out these plans, we interviewed officials at FDA headquarters and at the Centers.

To determine the elements necessary for an automated data processing system plan, we reviewed the Department of Health and Human Services' Information Resources Management Manual, Federal Information Processing Standards Publications, Office of Management and Budget circulars, and Department of Defense directives. See appendix II for further details on our scope and methodology.

During the course of our current review, we discussed the results of our work with FDA officials responsible for the activities being examined. W

have incorporated their comments in the report, as appropriate. We did not obtain official agency comments on a draft of this report. .

Our audit was conducted in accordance with generally accepted government auditing standards, from January 1989 through March 1989.

We are sending copies of this report to the Secretary of Health and Human Services; the Commissioner, Food and Drug Administration; the Chairmen, House Committee on Government Operations and Senate Committee on Governmental Affairs; and the Director, Office of Management and Budget.

This report was prepared under the direction of Melroy D. Quasney, Associate Director. Other major contributors to this report are listed in appendix III.

Daniel C. White

for Ralph V. Carlone
Assistant Comptroller General

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Abbreviations

ADP	automated data processing
COMIS	Center-wide ORACLE Management Information System
FDA	Food and Drug Administration
FIPS PUBs	Federal Information Processing Standards Publications
GAO	General Accounting Office
HHS	Department of Health and Human Services
IMTEC	Information Management and Technology Division

System Development Life-Cycle Phases and Related Documentation

Since we found that the Center for Drug Evaluation and Research has not prepared an ADP system plan, this appendix includes, as agreed, general guidance for accomplishing and documenting the tasks needed to develop such a plan.

An ADP system evolves in phases from the time that an idea to create the system occurs, through the time that the system is operational. Many different terms are used to identify the phases associated with creating and maintaining a system. The Department of Health and Human Services (HHS) requires its organizations to follow the National Bureau of Standards' Federal Information Processing Standards Publications (FIPS PUBs) in proceeding through the phases involved in developing automated data systems. FIPS PUBs 38 and 64 state that there are three phases in the automated data system life cycle: (1) initiation, (2) development, and (3) operation. In addition, FIPS PUB 65 and the HHS Information Resources Management Manual provide guidance for conducting required automated data system risk analyses.

The planning, design, development, and implementation of an ADP system represents a considerable investment of human and automated resources. Documentation provides information on system operation, training, maintenance, and system changes to support the effective management of ADP resources. It is important to promote, throughout the system development life-cycle process, communication and understanding among system managers, developers, programmers, operators, and users. The formality, extent, and detail of documentation prepared throughout the process should be commensurate with the size, complexity, and risk of developing a system.

Using the FIPS PUBs and HHS guidance mentioned above, we extracted a general description of the system development life-cycle phases and the documentation needed for establishing an ADP system plan. From these guidelines, we pulled together the following prototype, which describes the process needed to establish such a plan.

I. Initiation Phase

In this phase, the objectives and general definition of the requirements for the automated data system are established.

Documentation:

(1) Project Request Document:

(a) Provides the means for a user organization to request the development, procurement, or modification of automated data systems or other ADP-related services.

(b) Serves as the initiating document in the automated data system life cycle, and provides a basis for communication between the requesting organization and the receiving or processing organization to analyze requirements and assess impacts further.

(2) Feasibility Study Document:

(a) Provides

(1) an analysis of objectives, requirements, and system concepts;

(2) an evaluation of alternative approaches for reasonably achieving the objectives; and

(3) identification of a proposed approach.

(b) Should provide—in conjunction with the cost/benefit analysis document—management with adequate information to make decisions to initiate or continue the development, procurement, or modification of automated data systems or other ADP-related services.

(c) May be supplemented with an appendix containing details of a cost/benefit analysis, or may be considered with a separate cost/benefit analysis document.

(3) Cost/Benefit Analysis Document:

(a) Provides managers, users, designers, and auditors with adequate cost and benefit information to analyze and evaluate alternative approaches.

(b) In conjunction with the feasibility study document, should provide management with the information to make decisions to initiate or continue the development, procurement, or modification of automated data systems or other ADP-related services.

(c) May be prepared as a separate document, or details of the cost/benefit analysis may be appended to the feasibility study document.

(4) Risk Analysis Documents:

(a) Identify internal control and security vulnerabilities of an automated system.

(b) Describe the nature and magnitude of associated threats to data and assets.

(c) Provide managers, designers, systems security specialists, and auditors with recommended safeguards to be included during the design, development, and implementation phases of a new or modified automated information system.

(d) Should include detailed descriptions of all data and assets to be processed or accessed by the system to show their values or sensitivities.

(e) Should be reviewed and revised, as necessary, during each phase of the system development life cycle to assure that appropriate security measures are installed.

II. Development Phase:

In this phase, more detailed requirements are developed for the automated data system. Then, the automated data system is designed, programmed, tested, and documented.

(A) Definition Stage:

Documentation:

(1) Functional Requirements Document:

Provides a basis for the mutual understanding between users and designers of the initial definition of the automated data system, including the requirements, operating environment, and development plan.

(2) Data Requirements Document:

Provides a data description and technical information about data collection requirements.

(B) Design Stage:

Documentation:

(1) System/Subsystem Specification:

Specifies for analysts and programmers the requirements, operating environment, design characteristics, and program specifications (if desired) for a system or subsystem.

(2) Program Specification:

Specifies for programmers the requirements, operating environment, and design characteristics of a computer program.

(3) Data Base Specification:

Specifies the identification, logical characteristics, and physical characteristics of shared data elements.

(4) Test Plan:

Provides a plan for testing the automated data system, as well as detailed specifications, descriptions, and procedures for all tests; and test data reduction and evaluation criteria.

(C) Programming Stage:

Documentation:

(1) User's Manual:

Serves as a reference document for the user organization. It describes what the system does and how to use it.

(2) Operations Manual:

Provides instructions to computer operations personnel for operating the system.

(3) Program Maintenance Manual:

Provides the maintenance programmer with the information necessary to understand the programs, their operating environment, and their maintenance procedures.

(4) Test Plan:

Provides a plan for testing the automated data system, as well as detailed specifications, descriptions, and procedures for all tests; and test data reduction and evaluation criteria.

(D) Test Stage:

Documentation:

Test Analysis Report:

(a) Documents the test analysis results and findings.

(b) Presents the demonstrated capabilities and deficiencies for review.

(c) Provides a basis for preparing a statement of the automated data system's readiness for deployment.

III. Operation Phase:

The operational automated data system is maintained, evaluated, and changed, as additional requirements are identified and errors are detected and corrected. Maintenance activities will take the form of mini-system development efforts. For example, the activities will have functional specifications, test plans, user documentation, etc.

Documentation:

(1) Data libraries,

(2) Mission statements and agency and systems plans,

(3) Organization charts,

(4) Budgets,

(5) Position descriptions,

(6) Policies and procedures,

(7) Hardware and software inventories,

(8) System documentation reflecting the current state of the system as it is being operated,

(9) Contingency and backup plans,

(10) Internal control documentation,

(11) Test results,

(12) Maintenance records,

(13) Utilization reports,

(14) Operating logs,

(15) Minutes of relevant meetings, and

(16) Reports of audits, reviews, and studies.

Scope and Methodology

To determine if an FDA-wide automated data processing system plan exists that sets up a strategy for improving the quality and timeliness of medical device and drug application reviews, we interviewed officials in FDA's Division of Information Resources Management. We also reviewed the current FDA 5-year information resources management strategic plans to identify ongoing or planned activities specifically aimed at improving the review process for medical device and drug applications.

To determine if center-level automated data processing system plans exist, we interviewed officials at the Center for Devices and Radiological Health and the Center for Drug Evaluation and Research. To identify ongoing or planned activities aimed at improving the review processes and costs associated with these activities, we reviewed (1) both Centers' current 5-year information resources management strategic plans; (2) the Center for Devices and Radiological Health's 1987 report on the applicability of document image systems to FDA; (3) the 1988 automated data processing system plan for implementing document image technology at the Center for Devices and Radiological Health; and (4) the Center for Devices and Radiological Health's 1989 agency procurement request for document image system equipment.

To determine the extent to which the documentation we received from FDA officials adequately met system development standards, we compared it with guidelines from several sources. These guidelines included (1) the Department of Health and Human Services' Information Resources Management Manual; (2) Federal Information Processing Standards Publications 38, 64, 65, 73, 101, and 105; (3) Office of Management and Budget Circulars A-109 and A-130; and (4) Department of Defense Directives 7740.2, 7920.1, and 7920.2.

We discussed the results of our evaluation with the Director, Division of Information Resources Management, Office of Management and Operations; the Director, Office of Information Systems, Center for Devices and Radiological Health; the Director, Office of Management, Center for Drug Evaluation and Research; and officials of the Division of Information Systems Design, Center for Drug Evaluation and Research. We have incorporated their comments in the report, as appropriate. We did not obtain official agency comments on a draft of this report.

During our review, we did not attempt to assess whether the plan developed at the Center for Devices and Radiological Health or the efforts underway at the Center for Drug Evaluation and Research would

improve the quality and timeliness of medical device and drug application reviews.

We conducted our survey at FDA headquarters and FDA's Centers for Devices and Radiological Health, and Drug Evaluation and Research in Rockville, Maryland. Our audit was conducted in accordance with generally accepted government auditing standards, from January 1989 through March 1989.

Major Contributors to This Report

Information Management and Technology Division, Washington, D.C.

Melroy D. Quasney, Associate Director, (202) 275-4659
Douglas D. Nosik, Assistant Director
John A. Riley, Evaluator-in-Charge
Victoria L. Miller, Evaluator

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