UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

088949

MANPOWER AND WELFARE
DIVISION

JUL 19 1974

The Honorable Alexander M. Schmidt, M.D.
Commissioner, Food and Drug Administration
Department of Health, Education, and
Welfare

Dear Dr. Schmidt:

We have completed a survey of computer-based information systems at the Food and Drug Administration (FDA) with primary emphasis on the Program Oriented Data System (PODS) and its ability to meet user needs. The system is maintained by FDA's Division of Planning and Analysis (DPA), Office of the Executive Director for Regional Operations (EDRO), located in the Parklawn Building in Rockville, Maryland. We concentrated on PODS because it is one of the major computer-based systems in FDA in terms of computer resources used and is a management tool for planning, controlling, and evaluating the use of FDA's field resources.

PODS, which became operational in July 1967, reports accomplishments by FDA's district offices in the direct performance of the primary activities of the field force, such as establishment inspections, sample collections, and sample examinations. It also identifies conclusions reached as a result of these activities, such as, whether the firms are in compliance with FDA regulations. PODS reports, which are presented in a variety of formats to meet different user information requirements, show: (1) where the work was performed, (2) consumer protection problems covered, (3) position classes of employees engaged in field activities, (4) types of field activities performed, (5) commodities covered, and (6) time expended by the field force.

EDRO, regional and district offices, FDA bureaus, and the Office of the Commissioner use PODS information to compare field force accomplishments with the annual field workplan developed by EDRO in conjunction with the bureaus. The plan reflects the priorities set by the Commissioner, the Department of Health, Education, and Welfare and the Congress. PODS

7-19-74 088949

information is used to determine whether field obligations are being met and as a basis for redirecting the field effort. PODS historical information is used by EDRO and the bureaus to develop the annual workplan. For example, time expended to accomplish assigned tasks is used as a basis for allocating field resources and determining the number of tasks which can be accomplished in meeting the objectives of compliance programs developed by the bureaus. In addition, PODS information is used to respond to requests from external sources such as the Congress.

PODS input is provided by FDA's 19 district and field offices through terminals connected to a computer in FDA headquarters.

We interviewed 12 users of PODS information in FDA headquarters and 2 users in the Baltimore District Office. Seven of the 14 interviewed advised us that they were not satisfied with the timeliness of reports received from PODS. The need for timeliness varied with the users, and the remaining seven stated that PODS information was provided on time to meet their respective needs. Four of the 14 users informed us that they lacked confidence in the accuracy and/or completeness of the information because their prior experience indicated that the reports were inaccurate and incomplete.

EDRO has made several revisions to the system in an effort to more efficiently utilize the capabilities and features of the computer and telecommunications resources at FDA. These included (1) rewriting programs in a language which simplifies programing and training of programers which should enable the system to respond more rapidly to changes in information needs and requests for information, (2) using more efficient storage devices which reduce computer processing time significantly and which should provide more timely reporting, and (3) providing the capability for rapid feedback of errors to the district offices for correction. As a result, the time to produce monthly PODS reports has been significantly reduced. We were advised that before the changes were made monthly reports generally were made available to users 15 to 20 days after the close of each month. We noted that they can now be produced as early as the first working day after the close of each month.

EDRO is making further changes to improve PODS. Other major computer-based systems in FDA are also in various stages of development or revision and changes in the automatic data

processing organization are proposed to broaden the scope of services to Federal users in the Parklawn area. In view of these ongoing changes, we plan to defer further review of the effectiveness of computer-based systems at FDA. However, we wish to call your attention to certain matters that we believe should be considered as further efforts are made to improve FDA's information systems. These concern:

--The need for more current input to PODS.

--The need for a review function to promote timely resolution of problems.

TIMELINESS OF INPUT TO PODS

Although revisions made to PODS provide for more timely processing of reports, the changes in the system were not addressed adequately to include more current information in these reports.

We analyzed the timeliness of input submitted by the Baltimore District Office on three major activities--establishment inspections, sample collections, and sample examinations--for the first 7 months of fiscal year 1974. About 35 percent of the inspections, 15 percent of the sample collections, and 42 percent of the sample examinations were reported to PODS 2 or more months after they were performed. The vast majority of these were reported after 2 to 4 months, but in some cases the reporting lag was from 5 to 9 months. Several users indicated to us that a 1-month reporting lag was generally acceptable for monitoring accomplishments, but that a longer lag could diminish the value of the information.

We brought this matter to the attention of DPA. As a result, DPA analyzed the input lag on inspections on a nationwide basis for the first 7 months of fiscal year 1974. DPA's analysis showed that delays in input existed in several district offices.

We did not explore in detail the reasons for the input lag. However, Baltimore District Office personnel stated that two major contributing factors to the input lag were (1) errors made in the preparation of source documents by district office personnel which, when detected by the Data Processing Unit in Baltimore, were returned to the originators for correction; and (2) backlog of supervisory review of source documents,

particularly inspection reports. This would seem to indicate the need for more simplified source documents and instructions for their preparation as well as the need to study the impact of the supervisory review process on the input lag.

The Director, DPA, advised us that a consultant under contract with FDA has initiated a study of PODS source document design and paperflow process in the district offices as a basis for improving the input lag. We were also advised that EDRO will institute changes in fiscal year 1975 in the procedures for inputting data on sample examinations which should contribute to reducing the input lag for that activity.

PROVISION FOR REVIEW OF AUTOMATED SYSTEMS

FDA plans to establish a Parklawn Computer Center which will be administered by FDA's Office of the Associate Commissioner for Administration. The Center will provide automatic data processing services on a fee-for-service basis to Federal agencies headquartered in the Parklawn area. The preliminary plans for the Center provide for a Project Advisory Staff to be assembled on an ad hoc basis to perform independent audits of the Center's operations and of the agencies' use of the Center. The Project Advisory Staff, which will consist of specialists in the particular areas being studied or evaluated, will report to a proposed User Steering Committee composed of the chief administrative officers from each major Parklawn user agency.

We believe that the proposed Project Advisory Staff has merit and the potential to provide the stimulus for timely resolution of problems with automated systems that are not meeting user needs.

Timeliness of reporting was a problem with PODS users as early as 1971. The Assistant Commissioner for Field Coordination (now EDRO) initiated a user study in January 1971 with the objective of changing PODS to furnish users with information they needed on a timely basis.

The study disclosed that several users in FDA headquarters and in the field expressed the need for more timely PODS reporting. However, at least 2 years elapsed before the necessary changes were made to the system. During the 2 years, EDRO continued its user studies and performed design work on a Field Activities Computer Teleprocessing System (FACTS) to replace PODS.

FACTS was to integrate PODS and other computer-based information systems in EDRO and correct deficiencies in PODS enumerated by the users. By March 1973, however, little progress had been made on FACTS, and problems continued to exist with PODS. FDA's Automatic Data Processing Systems Policy and Operations Center reviewed the system design for FACTS and concluded in March 1973 that the system existed in conceptual terms only and that it exceeded the capabilities of the automatic data processing resources at FDA.

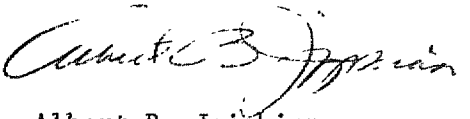
EDRO reevaluated FACTS and decided that a "bridge" was needed between PODS and FACTS to resolve the immediate problems of time consuming processing, inaccuracies in reports, and lack of user interaction with the system. In April 1973 EDRO deferred further work on FACTS and began work on reprograming and redesigning PODS. PODS as subsequently revised is known as PODS II. The Director, DPA, advised us in April 1974 that no further work will be done on FACTS and that future work will involve further refinement of PODS.

We believe that the proposed concept of a Project Advisory Staff drawn from the user community will provide a mechanism for more timely resolution of problems with computer-based information systems. In our opinion, such a function has the potential to substantially reduce the timeframe required to resolve problems such as those encountered with PODS if appropriate followup is made by FDA management to ensure that action is taken on the Staff's findings.

- - - -

We appreciate the cooperation and courtesy extended to us by FDA personnel during our survey and we would appreciate any comments you may have regarding the matters discussed in this report.

Sincerely yours,



Albert B. Jojokian
Assistant Director