Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

COMPUTER SUPPORT FOR FDA'S DRUG REGISTRATION AND LISTING SYSTEM

MANAGEMENT ADVISORY REPORT

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EXECUTIVE SUMMARY

PURPOSE

This report describes the Food and Drug Administration's (FDA) computer support for its Drug Registration and Listing System (DRLS). A companion report is entitled, "The FDA Prescription Drug File" (OEI-03-90-02300).

BACKGROUND

The DRLS has two components. The registration component collects information on the registration of establishments which manufacture and/or distribute drug products in the United States market, while the listing component collects drug product data.

The registration and listing information is required by the Drug Listing Act of 1972. It is also the cornerstone for other databases in FDA's Center for Drug Evaluation and Research.

In 1989, the Office of Inspector General used DRLS prescription drug data and noticed it did not match data from other sources. The discrepancies led to the report, "The FDA Prescription Drug File," and to this report which describes the computer system.

FINDINGS

Due to data integrity problems associated with its computer system, FDA is implementing a new one.

The registration component is already on line in new software, and the system appears adequate.

The listing component is still in the planning stage of conversion. Until the conversion is completed, accuracy problems associated with the older system will persist.

FUTURE ACTION

The FDA appears to be moving in the right direction with the overhaul of the computer system. However, since the planning and conversion is incomplete, we cannot determine the overall adequacy of the new system or make recommendations.

Regular review of progress by FDA can help ensure that the new system meets their needs. We hope to look at the system once the entire conversion is completed.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

FINDINGS

INTRODUCTION

PURPOSE

This report describes the Food and Drug Administration's (FDA) computer support for its Drug Registration and Listing System (DRLS). A companion report is entitled, "The FDA Prescription Drug File" (OEI-03-90-02300).

BACKGROUND

The DRLS is FDA's system for collecting and managing information required by the Drug Listing Act of 1972, as set forth in 21 CFR, Part 207. The information falls into two categories:

- Registration -- Includes drug company information such as name and address, type of operation (e.g., manufacturer, distributor), registration number, and labeler code.

- Listing -- Includes drug product information such as trade name, legal status (e.g., prescription, over-the-counter), dosage form, ingredients, and National Drug Code (NDC). The NDCs are unique identifiers of a product, its manufacturer or distributer, and its package size.

Most DRLS information is stored in computer files. These files make up a database which is the cornerstone for other databases in FDA's Center for Drug Evaluation and Research. The other databases are:

- "The Drug Product Reference File." This database is used for the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as "the Orange Book." It is linked to the DRLS field for drug ingredient codes.

- "The Adverse Reaction Reporting System." This is another database linked to the DRLS field for drug ingredient codes.

- "The Drug Quality Reporting System." This is linked to the DRLS by the NDC field.

- "The Developers and Distributors System." This database is made up of company names and addresses from the DRLS.

Information from the DRLS has many uses. It aids the work of FDA district inspectors as well as State compliance agencies. It has been used by the drug industry, third-party health plans, the Health Care Financing Administration, the Drug Enforcement Agency, and the General Accounting Office.

In 1989, we used DRLS prescription drug data and noticed it did not match data from other sources. The discrepancies led to the 1990 inspection of the DRLS prescription drug file (report number OEI-03-90-02300). During the same period, we conducted the inspection of the computer system for all DRLS files.

This report describes the computer system in place during our inspection, as well as a new system FDA is implementing.

METHODOLOGY

We reviewed FDA documentation and memoranda pertaining to the DRLS computer system. We also conducted on-site and telephone interviews with FDA staff in the Drug Listing Branch and the Division of Information Systems Design (DISD). The Drug Listing Branch is responsible for processing registration and product data and keying it into computer files; the DISD designs and implements computer programs and systems. Documents and interviews provided us with information about FDA's computer programs, systems, current problems, and plans for change and improvement.

We conducted this inspection with the assistance of an outside consultant who is a computer expert. In May 1991, our consultant prepared a technical report entitled, "Evaluation of Computer Hardware and Software for FDA's Drug Listing," which we have shared with program staff at FDA.

FINDINGS

DUE TO DATA INTEGRITY PROBLEMS ASSOCIATED WITH ITS COMPUTER SYSTEM, FDA IS IMPLEMENTING A NEW ONE.

The FDA began a two-stage overhaul of the DRLS computer system in the spring of 1990. The registration data was the beneficiary of the first stage which was completed in the spring of 1991. The listing data will be affected in the second stage which is currently in progress.

The old computer system was inadequate for the DRLS and caused data integrity problems. Major inadequacies of the system were with the database management software and the database structures.

Database management software

Database management software determines how data is entered and retrieved. The DRLS was managed by "first-generation," or early model, software which does not have on-line access for data entry and retrieval. Data entry was by keypunching, and data retrieval was by printouts. All data files were stored on a mainframe computer located at a different site from the Drug Listing Branch.

The lack of on-line access delayed updates to data records, diminished opportunities to find and correct errors, and prevented timely availability of data. It took several weeks or months from the time data arrived from the drug industry to the data's appearance in a computer printout.

Since the DRLS is the cornerstone for other FDA databases, the DRLS computer system affects the reliability of those databases as well. If DRLS drug records are not updated quickly, the wrong information is likely to be picked up by the other databases.

All DRLS records are being transferred to "second generation," or newer model, database management software which has on-line access. In addition, terminals are being installed so that authorized personnel can access different on-line services (e.g., maintenance, data entry, and information retrieval). These changes will solve problems associated with data entry and retrieval delays.

Database structures

A database structure defines what data will be stored, and it influences data interpretation. Once in place, a structure is rarely changed. It includes the formats, properties, and interrelationship of database records. Categories for data and the number and sizes of information fields, for example, are part of the structure.

The DRLS structures for the registration and listing data were not able to hold sufficient data. This led to data integrity problems.

To solve the problems of insufficient data, the structures are being redesigned. The new structures will also eliminate redundant storage of data in related databases. Redundancy wastes computer resources and leads to loss of data integrity when one copy of the data is updated and another is not.

THE REGISTRATION COMPONENT IS ALREADY ON LINE IN NEW SOFTWARE, AND THE SYSTEM APPEARS ADEQUATE.

The new system for registration data was being implemented while this inspection was underway. With on-line services, staff can enter and retrieve data at computer terminals.

The new database structure has chronology fields which allow for data entry while confirmation of data is still in progress. Staff do not have to wait for time-consuming checks to be completed before entering new information; they can enter the data upon receiving it. Data in chronology fields will indicate when and if the checks have been completed. This new feature will prevent data entry delays.

Another benefit of the chronology fields is the ability to show when a given NDC has been removed from circulation. It will permit a firm's data to remain on record while making it clear that the firm's NDC is no longer active.

The new database structure also has identification of key fields, which are assigned artificially by the system, to avoid problems associated with nonexistent registration numbers or duplicate NDCs. Firms can now appear in the database without a registration number or with an NDC duplicated by a more current firm.

THE LISTING COMPONENT IS STILL IN THE PLANNING STAGE OF CONVERSION.

The volume and variety of product listing data are much greater than registration data, and the management of the data is more complicated. The FDA does not expect the overhaul of the listing component to be completed for at least another year.

At the time of our review, on-line service was available for product listing in a limited way. Selected staff, for example, had a query screen to verify an active product's NDC.

The structure design was still in the planning stage. Until a design is approved and listing integrated into the new database management software, accuracy problems associated with the older system will persist.

FUTURE ACTION

Recognizing the DRLS computer system was inadequate, the FDA embarked on planning and implementing a new one. The new system is expected to solve data integrity problems identified with the old system.

The FDA appears to be moving in the right direction. However, since the planning and conversion is incomplete, we cannot determine the overall adequacy of the new system or make recommendations.

Regular review of progress by FDA can help to ensure that the new system meets their needs. We hope to look at the system once the entire conversion is completed.