

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**THE FDA PRESCRIPTION DRUG FILE**



NOVEMBER 1991

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# EXECUTIVE SUMMARY

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## PURPOSE

This report describes the completeness and accuracy of the prescription drug file in the Food and Drug Administration's (FDA) Drug Registration and Listing System (DRLS). A companion report describes FDA's computer support for all DRLS files (OEI-03-90-02301).

## BACKGROUND

The Drug Listing Act of 1972 (P.L. 92-387) requires drug firms to provide FDA with data on all commercially distributed drugs. This information is maintained in the files of a computer database called the DRLS. Products are listed in the drug file by their National Drug Code (NDC).

The DRLS has many uses. As a catalog of drug firms and products, it was used in recent generic drug investigations and in the Defense Department's Operation Desert Storm. In the latter case, staff identified products containing antidotes for poison gas and their manufacturers.

This report focuses on the DRLS prescription drug file of 39,000 products and its status as of March 1990.

## METHODOLOGY

We (1) compared NDCs in the drug file with those in a private database file, (2) analyzed random samples of nonmatching NDCs in each file, (3) called drug firms about the market status of these products, (4) examined documents submitted to FDA by drug firms, and (5) interviewed FDA staff on site.

## FINDINGS

*The drug file is not complete or totally accurate.*

We estimate more than 8,000 additional products were on the market but missing from the file. Approximately 1,400 products were in the file but off the market.

*Drug firms do not always supply the required data.*

*Deficiencies at FDA also cause or compound drug file errors.*

- ▶ Legal requirements for industry to return Compliance Verification Reports are unclear.
- ▶ Data requirements for industry are unclear.

- ▶ Quality control is lacking, and the computer software system is inadequate.
- ▶ There is a shortage of staff, space, supplies, and equipment.

*The FDA is taking steps to improve the drug file.*

Drug listing instructions are being improved; quality control is being addressed; and a new computer system designed.

## **RECOMMENDATIONS**

The FDA should:

- ▶ Clarify and strengthen its legal authority to take regulatory action against firms that do not return Compliance Verification Reports.
- ▶ Clarify data requirements for industry.
- ▶ Develop internal quality control procedures for manual data processing.
- ▶ Ensure that maximum benefits result from the new computer software system.

## **COMMENTS FROM PUBLIC HEALTH SERVICE (PHS)**

The PHS concurs with the report's findings and recommendations. The full text of comments from PHS appears in the appendix.

# TABLE OF CONTENTS

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## EXECUTIVE SUMMARY

INTRODUCTION ..... 1

## FINDINGS

The drug file is not complete or totally accurate ..... 5

Drug firms do not always supply the required data ..... 5

Deficiencies at FDA also cause or compound  
drug file errors ..... 6

The FDA is taking steps to improve the drug file ..... 8

RECOMMENDATIONS ..... 9

APPENDIX: COMMENTS FROM PUBLIC HEALTH SERVICE ..... A-  
1

# INTRODUCTION

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## PURPOSE

This report describes the completeness and accuracy of the prescription drug file in the Food and Drug Administration's (FDA) Drug Registration and Listing System (DRLS). A companion report describes FDA's computer support for all DRLS files (OEI-03-90-02301).

## BACKGROUND

### *The DRLS and its uses*

The Drug Listing Act of 1972 (P.L. 92-387), as set forth in 21 CFR, Part 207, requires the drug industry to provide FDA with data on all drug firms and drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution in the United States. The FDA maintains this information in a database called the DRLS.

The DRLS has many uses. As a catalog of drug firms and products, it was used in recent generic drug investigations and in the Defense Department's Operation Desert Storm. In the latter case, FDA staff identified products containing antidotes for poison gas and their manufacturers. During episodes of product tampering, staff located sites where affected products were manufactured and distributed (e.g., when Tylenol capsules were laced with cyanide in the 1980s).

In recent years, the DRLS assisted the Health Care Financing Administration (HCFA) in a search for products that are not effective for their intended uses and, therefore, not reimbursable. In connection with new Medicaid drug rebate regulations, HCFA relied on the DRLS for a list of prescription drug manufacturers in each State.

Other DRLS users include the Drug Enforcement Agency, Federal Bureau of Investigation, offices of poison control, school nurses, and physicians. The DRLS is also the basis for The National Drug Code Directory which is used by third party reimbursement programs to identify drug products.

The DRLS has two major components. The registration component contains files on drug firms, while the drug listing component is divided into three drug product files: prescription, over-the-counter, and bulk products. The prescription file is the most up-to-date of the product files, according to FDA.

This report focuses on the prescription file and its 39,000 active products as of March 1990. We refer to that file in this report by the shorter term "drug file."

### *Drug file data*

Drug file data is submitted to FDA by the drug industry. It includes, but is not limited to, trade name, ingredients, dosage form, and strength. New product information is supplied on forms, while data on changed or discontinued products is on forms or on Compliance Verification Reports.

Compliance Verification Reports are computer printouts generated from the drug file and mailed to drug firms. Each report contains a particular firm's product data as it appears in the file. The firm's responsibility is to verify the information and mail the report back to FDA, along with additional data on new, changed, or discontinued products.

Before any data is keyed into the drug file, it is processed manually. Numerous staff members handle the forms and Compliance Verification Reports in a complicated process of sorting, researching, and adding information.

### *Private database files*

The drug file is not the only source of prescription drug data. Private companies also maintain drug databases. The private files have different uses than the FDA file. They contain pricing information and are sold to States and other entities involved with drug pricing issues.

Drug firms voluntarily provide information to these private databases so that their prices will be available to buyers of the files.

### *National Drug Codes (NDCs)*

Each drug product has a unique 10-digit number known as an NDC. The NDC identifies: (1) the firm that manufactures or distributes the product; (2) the product (specific strength, dosage form, and formulation); and (3) the package size.

The NDC is the basis for all third-party reimbursement. The FDA uses it as an access code for various computer databases and as a hard copy filing number for drug listing forms and Compliance Verification Reports. In our study, NDCs were a key for determining the accuracy and completeness of the drug file.

### *Prior Office of Inspector General studies*

In 1989, we used the FDA drug file for two studies of Medicaid program compliance with prescription drug regulations.<sup>1</sup> At that time, we noticed three discrepancies between data in the drug file and State Medicaid programs: (1) some NDCs that were identical in the drug file and State lists represented different products; (2) some NDCs in the State lists were missing from the drug file; and (3) some NDCs in the drug file represented more than one product. These discrepancies were the impetus for the current study.

### **SCOPE AND METHODOLOGY**

The study was conducted between March 1990 and April 1991, and it focused on the March 1990 status of the active drug file. We did not examine other DRLS files.

To determine if products were missing from the drug file and if products in the file were off the market, we: (1) compared FDA's file with a private file used by many State Medicaid programs, and (2) contacted drug firms about the status of their products. We did not evaluate the private file for completeness and accuracy. It was used only to identify additional NDCs.

First, we compared all the NDCs in both files in order to identify ones that did not match. The nonmatching NDCs fell into the following categories:

- ▶ **16,700**      ***Products in private file only***
  - 15,200      Products manufactured/distributed by firms listed in both files
  - 1,500      Products manufactured/distributed by firms listed in private file only
  
- ▶ **14,000**      ***Products in FDA's file only***
  - 5,500      Products manufactured/distributed by firms listed in both files
  - 8,500      Products manufactured/distributed by firms listed in FDA's file only

Next, we developed three sample groups for further inspection.

Group 1:      200 products randomly selected from the universe of 15,200 products in the private file only, but which were manufactured/distributed by firms listed in both the FDA and private files.

Group 2:      All 1,500 products which were listed only in the private file, and which were manufactured/distributed by firms (129) listed only in the private file.

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<sup>1</sup>The report numbers are A-03-89-00220 and A-03-89-00213.



Group 3: 200 products randomly selected from the universe of 5,500 products which were listed only in FDA's file, but which were manufactured/distributed by firms in both files.

We contacted every drug firm (about 300) with products in these three sample groups to determine whether the products were actually on the market.

From sample groups 1 and 2, we identified products that were on the market but missing from FDA's file. From sample group 3, we identified products that were off the market and still in FDA's file. We did not sample the 8,500 products manufactured/distributed by firms listed in FDA's file only. While a review of this category may have identified additional products that were off the market but still in FDA's file, it would also have indicated which products were missing from the private file and that was not our purpose.

To identify causes of drug file errors, we examined FDA's files of drug listing forms and Compliance Verification Reports for all products in our three sample groups. We also examined the hard copy filing system for these documents and related correspondence, and conducted on-site interviews with FDA staff who handle the drug data.

# FINDINGS

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## **THE DRUG FILE IS NOT COMPLETE OR TOTALLY ACCURATE.**

As of March 1990, the file contained 39,000 products. Based on our analysis:

- ▶ We estimate more than 8,000 additional products were on the market but missing from the file.

As mentioned previously, we took a random sample of 200 products from the universe of 15,200 products in the private file but not in FDA's file. Of the 200 sampled products, 104 (or 52 percent) were actually marketed, according to the drug firms. Applying this error rate to the universe, we estimate about 7,900 products are missing from FDA's file (90 percent confidence interval, 6,982 - 8,801).

From the 1,500 products handled by firms listed in the private file only, we found another 350 products (representing 37 drug firms) were marketed but missing from FDA's file. If all the identified missing products (7,900 + 350) were listed in FDA's file, it would increase by 21 percent.

- ▶ We estimate 1,400 products in the file were off the market.

As mentioned previously, we took a random sample of 200 products from the universe of 5,500 products in FDA's file but not in the private file. Out of the sample, 52 products (or 26 percent) were off the market, according to the drug firms. They should not have been listed in FDA's active file. Applying this error rate to the universe, we estimate 1,400 products (4 percent of the file) are inaccurately listed (90 percent confidence interval, 1,135 - 1,699).

## **DRUG FIRMS DO NOT ALWAYS SUPPLY THE REQUIRED DATA.**

We examined FDA's files to determine if the 165 drug firms in our two sample groups of randomly selected products were submitting the required forms and Compliance Verification Reports. We found that:

- ▶ Drug firms had not submitted listing forms for about three-fourths (74 percent) of the sampled products which were missing or inaccurately listed. As noted in the previous finding, 104 products were missing and 52 products were inaccurately listed.
- ▶ Forty-five (27 percent) of the 165 sampled firms did not submit Compliance Verification Reports.
- ▶ Sixty-six (55 percent) of the 120 firms that submitted Compliance Verification Reports left one or more products off the report.

## **DEFICIENCIES AT FDA ALSO CAUSE OR COMPOUND DRUG FILE ERRORS.**

Through on-site observation, document reviews, and staff interviews, we found the deficiencies described below. Many of these are interrelated.

### ***Uncertainty of legal authority***

While Compliance Verification Reports are not explicitly mentioned in 21 CFR 207.22(b), FDA treats the non-return of these reports as violations of this section of the CFR. The section states that firms must update their product data on Form FDA-2657. There is some question as to whether this CFR section requires industry to submit data on Compliance Verification Reports.

### ***Inadequate forms and instruction booklet***

Drug listing forms are confusing and inadequate. One form, for example, which provides data on a product's private label distributors, does not require the distributors' addresses. Without the addresses, FDA cannot mail Compliance Verification Reports to those firms. Consequently, any errors in the data will not be caught and corrected.

The DRLS Instruction Booklet is difficult to understand and does not contain all the information drug firms need. For example, the booklet lacks an explanation of the Compliance Verification Report. This missing information is significant because FDA interprets an unreturned Compliance Verification Report as a violation of Federal regulations.

### ***Lack of quality control in data processing***

Product information is inaccessible for many weeks. No record is made of any data from the time a form arrives at FDA until it reaches the end of a long and complicated manual processing chain. Furthermore, forms cannot be located while they are in the chain. This creates an environment where individuals who handle the forms are not held accountable for errors or loss of data.

In the case of Compliance Verification Reports, staff lack a systematic and reliable way to track how many and which firms return them on time, late, or not at all. Even when staff know which firms have not returned Compliance Verification Reports, they do not routinely mail delinquent notices.

### ***Incomplete procedural guides***

A complete set of procedural guides does not exist. Piecemeal guides are in writing for some aspects of data processing. But most interviewed staff did not know of their existence. They rely primarily on custom to execute their jobs.

Some staff use printed Federal regulations for guidance, and all refer to the DRLS Instruction Booklet. The booklet, however, was designed for industry's use. While it describes how firms should report product information to FDA, it does not contain procedures for researching product data, processing incoming forms, or handling special cases and problems.

### *Inadequate software system*

The computer software system for DRLS drug files is inadequate for FDA's needs, according to computer experts. The system does not allow for entering and modifying data at different stages in the manual processing chain. This contributes to the previously mentioned inaccessibility of product data.

Another shortcoming of the system is that drug files cannot be viewed on computer monitors. Staff use cumbersome printouts of drug data to look up information. These printouts resemble oversized telephone directories and are used in much the same way.

Under this system, over 3,000 product entries were lost in 1987 and 1988. According to FDA staff, the loss occurred during the transmittal of data from terminal files to the mainframe computer where the DRLS is housed.

### *Insufficient staff, space, supplies, and equipment*

Since 1986, full time staffing has been reduced from 26 to 22. During the same time, workload has increased. New work for staff includes (1) determining if new drug listings from manufacturers are for unapproved drugs, (2) cataloging less-than-effective drugs, and (3) cataloging drugs that are identical, related, or similar to less-than-effective drugs.

Overcrowded conditions in the file room make filing and retrieving difficult. Forms are tightly packed on shelves in a small area, increasing the risk of damage and loss.

A shortage of office supplies and equipment contributes to inefficiency. Staff lack the most basic supplies like file folders and date stamps, and there are only two personal computers. Work involving accounting, bookkeeping, and report writing is still done with paper and pen. Thus, time is spent on numerous manual tasks that could be done more quickly and accurately with computers.

### **THE FDA IS TAKING STEPS TO IMPROVE THE DRUG FILE.**

The FDA is aware of the deficiencies noted in the previous finding and has been taking some steps to address them.

### *Improving drug listing instruction*

To reduce drug industry errors on listing forms, FDA staff led five instructional seminars for industry professionals during 1990. In March 1991, clearer directions were drafted for a reprint of the DRLS instruction booklet.

*Drafting operating procedures*

Operating procedures for certain data processing staff were in draft as of February 1991.

*Addressing quality control issues*

As of December 1990, a staff person was assigned to review new product forms before keyers enter data into the computer. This individual checks for obvious errors or omissions on the forms.

Two tracking systems are being developed. One will track forms during manual processing. The other will track industry's return of Compliance Verification Reports.

*Converting the software system*

In 1990, FDA began converting DRLS files to a new computer software system which has many on-line services. While the registration files are almost fully converted, the drug files are still in the old system.

A design for the drug file conversion is now in the planning stage, and it is not yet known what effect the conversion will have on manual data processing. Some on-line drug data became available for selected staff late in 1990. If the number of staff performing the conversion remains the same, all drug files may be in the new system by the end of 1992.

# RECOMMENDATIONS

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The FDA should:

- ▶ **Clarify and strengthen its legal authority to take regulatory action against firms that do not return Compliance Verification Reports.**

If FDA does not have authority, it should seek this through regulatory change. In addition, FDA should seek legislative authority to assess penalties against noncomplying firms to cover enforcement costs.

- ▶ **Clarify data requirements for industry.**

This could be done by revising the drug listing forms and instruction booklet.

- ▶ **Develop internal quality control procedures for manual data processing.**

A first step could be to make a complete set of operating procedures available for all staff.

- ▶ **Ensure that maximum benefits result from the new computer software systems.**

While the conversion of drug files is in the design stage, consideration could be given to (1) keying drug data early in the processing chain, (2) minimizing manual processing errors through computer applications, and (3) planning for future enhancements.

# APPENDIX A

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## COMMENTS FROM PUBLIC HEALTH SERVICE (PHS)

The PHS concurs with our report's findings. It also concurs with our recommendations and has taken, or is taking, action to implement them.

The full text of comments from PHS are included in this appendix.