United States General Accounting Office

GAO

Report to the Secretary of Health and Human Services

September 1986

FOOD AND DRUG ADMINISTRATION

Laboratory Analysis of Product Samples Needs to Be More Timely

GAO/HRD-86-102

GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-224625

September 30, 1986

The Honorable Otis R. Bowen, M.D.
The Secretary of Health and Human Services

Dear Mr. Secretary:

In prior reviews we found that the Food and Drug Administration (FDA) has not been able to identify violative products and remove them from the market in a timely manner. Reasons for this included FDA's lack of authority to detain products, the long time FDA takes to process product samples through its field offices, and the long time FDA headquarters takes to review and approve field office recommended regulatory actions. The impact of sample processing delays was that, as the time frame increased, so did the amount of violative products reaching the consumer.

This report discusses the time FDA's field laboratories take to process product samples, the impact that delays have on FDA's ability to take appropriate regulatory action on violative products, and improvements needed to speed up the process.

As you know, 31 U.S.C. 720 requires the head of a federal agency to submit a written statement on actions taken on our recommendations to the Senate Committee on Governmental Affairs and the House Committee on Government Operations no later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We are sending copies of this report to the chairmen of the above-mentioned committees and other interested congressional committees and subcommittees. Copies are also being sent to the Director, Office of Management and Budget; the Commissioner of FDA; and other interested parties.

Sincerely yours,

Richard L. Fogel
Assistant Comptroller General

Executive Summary

Purpose

A primary responsibility of the Food and Drug Administration (FDA) is to protect the American consumer from adulterated or misbranded (violative) products. The role of FDA's field laboratories in accomplishing this mission is critical. They test numerous samples of products for possible violations. When violative products are identified, FDA takes regulatory actions, including seizures, to remove them from the market.

Removing violative products from the market through seizure takes time. As the time frame for action increases, so does the amount of violative products reaching the consumer.

This report discusses (1) the timeliness of field laboratories in processing product samples to determine if they are violative and (2) measures that can be implemented to bring about improvements.

Background

Investigators from FDA district offices collect the samples that field laboratories test. The investigators either carry or ship the samples and collection reports to the laboratory responsible for testing them. On receipt, the samples are placed in a locked storage area and entered in the laboratory's sample inventory.

After receiving the collection report on a sample, a laboratory manager gives the sample a priority ranking and assigns it to an analyst for testing. The sample is tested using a prescribed method, and the analyst prepares a written report. The report is checked by a laboratory supervisor for testing method suitability, accuracy of calculations, overall accuracy, and completeness. The supervisor also determines whether the product is violative, based on the test results.

Samples collected by FDA for field laboratory analyses are classified into two broad categories—compliance samples, which FDA believes have a high likelihood of being violative, and surveillance samples, collected to obtain safety and other data about selected products from a local or national perspective.

To assess the timeliness of sample processing, GAO obtained and analyzed data on 82,491 samples processed by FDA's field laboratories during the 18-month period October 1, 1983, through March 31, 1985. GAO determined the total time the samples spent in the laboratory, from receipt of the sample to reporting the test results out of the laboratory, including the time each sample spent in the inventory waiting to be tested.

Results in Brief

A key to removing adulterated or misbranded products from the market is the timely processing of products through the laboratory. FDA has not given its laboratories sufficient guidance on how quickly such products should be processed. Thus, the laboratories did not process products quickly enough, resulting in adulterated or misbranded products reaching the market. GAO's analysis showed that the laboratories took an average of 28 calendar days to complete product processing. This did not include the time needed to collect the sample and take legal action to seize the violative products.

GAO previously proposed that the Congress consider giving FDA broader detention authority to help keep violative products off the market because products were being sold or distributed before an approved seizure order could be obtained. FDA believes the detention period, which should begin when an FDA investigator collects a sample of a product believed to be violative, should be 30 days. If FDA were given this broader detention authority, laboratory processing time would have to be shortened significantly to allow enough time for FDA to carry out necessary legal action to seize the violative products within this detention period.

Several managerial initiatives could be taken to improve the laboratories' timeliness. Among them are establishing time-frame guidelines for the processing of all products, improving management of the controllable workload in the laboratories, and reducing the paperwork requirements for recording the results of noncritical tests. These actions could result in improved productivity and better responsiveness when time is of the essence.

Principal Findings

Reasonable Sample Processing Time Frames Should Be Established

During the 1970's FDA established sample processing time frames for domestic and import compliance samples. However, it later deemphasized the time frames for domestic compliance samples because it believed some laboratory analysts were compromising quality to meet the time frames. The time frames for import samples have remained in effect. FDA has not established time frames for processing surveillance samples, which account for about one-half of all samples field laboratories test and one-fourth of those identified as violative.

GAO's analysis of FDA data for 82,491 samples showed an average of about 28.4 calendar days for laboratory processing This ranged from about 8.5 days at one laboratory to about 87.6 at another. In addition, upon comparing laboratory processing time for 12,501 non-microbiological import compliance samples to the established import sample timeframe guidelines (3 to 6 days), GAO found that 8,040 samples, or 64 percent, exceeded them. Of the 19 laboratories, 14 exceeded the guidelines for 50 percent or more of the samples processed. Case files for violative samples identified by three laboratories showed that processing delays continued to result in violative products reaching the market.

Sample Inventory Needs Better Control

For the 82,491 samples discussed above, almost half of the average laboratory processing time (13.3 of the 28.4 calendar days) was inventory time—the time a sample was waiting to be tested. Average inventory times ranged from 2.9 days at one laboratory to about 48.6 at another.

The size of sample inventories was permitted to become too large, thus precluding timely processing for all samples. Inadequate control over inventory size stemmed from the laboratory managers (1) not controlling the rate at which samples are received from their district's investigations branch and (2) not coordinating the flow of samples received from other districts with the laboratories' abilities to analyze them.

Sample Testing Documentation Requirements Burdensome

Documentation requirements are another obstacle to achieving more timely sample processing. Current requirements involve extensive documentation for most samples that add an estimated minimum of one-half hour of analyst time for each sample tested. FDA permits abbreviated reporting for certain sample categories; however, the use of abbreviated reporting varied among laboratories. Requiring abbreviated reporting for nonviolative, surveillance samples could save FDA about 11.5 staff years of analyst time annually.

Recommendations

GAO recommends that the Secretary of the Department of Health and Human Services (HHS) direct the Commissioner of FDA to develop and implement guidelines for the timely processing of all samples by field laboratories.

GAO further recommends that the Secretary direct the Commissioner to (1) establish procedures requiring district offices to coordinate and

schedule the collection of surveillance samples and a policy that prohibits the collection and delivery to the laboratories of large numbers of samples in order to meet collection quotas and (2) reduce, to the extent practicable, formal reporting requirements for nonviolative, surveillance samples.

Agency Comments

In an August 8, 1986, letter, HHS agreed with most of GAO's recommendations HHS stated that FDA will appoint a task force to review this report and its recommendations, study field laboratory management, and propose policies and practices to enhance laboratory operations.

The task force will (1) review sample processing time frames and priorities and the computerized laboratory management system, (2) examine the potential for using abbreviated reporting on a field-wide basis for surveillance programs, and (3) consider the impact that placing large numbers of surveillance samples into the inventory has on the timely analysis of all samples.

Contents

Appendixes

Tables

Abbreviations

FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
HHS	Department of Health and Human Services

Introduction

One of the Food and Drug Administration's (FDA's) primary responsibilities is to protect American consumers by keeping and removing adulterated and misbranded products from the market. FDA's success depends largely on its ability to identify and remove quickly from the market products suspected or known to be adulterated or misbranded. FDA's basic authority for accomplishing this responsibility is derived from the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, as amended (21 U.S.C. 301). The act specifically prohibits the distribution in interstate commerce or importation of products that are adulterated or misbranded.[1] (In this report, we refer to these as violative products.)

FDA consists of a headquarters staff, 10 regional offices, and 22 district offices located throughout the country and Puerto Rico. Four headquarters centers,[2] in conjunction with the Office of Regulatory Affairs, establish the basic policies FDA uses in implementing its regulatory activities. The Office of Regional Operations, based on policies established by the Office of Regulatory Affairs and the four centers, is responsible for coordinating the inspection, testing, and enforcement activities of FDA's field operations.

FDA's field laboratories have a critical role in protecting the consumer from violative products. These laboratories test numerous samples of products for possible violations. When violative samples are identified, FDA takes appropriate regulatory actions, including seizures, to remove them from the market.

Removing violative products from the market through seizure actions takes time, and delays often occur between when the FDA investigator initially identifies the problem and when the seizure order is executed. Consequently, the impact of delays on the effectiveness of seizure actions is that, as the time frame increases, so does the amount of violative products reaching the consumer.

In September 1984, we reported that FDA actions to seize violative food products from the market were not fully effective and proposed that the Congress consider authorizing FDA to detain suspected violative food

[1]An adulterated product is defective, unsafe, filthy, or not produced in conformance with good manufacturing practices. A misbranded product has labeling that is false or misleading or that fails to provide important and/or required information.

[2]Center for Food Safety and Applied Nutrition, Center for Drugs and Biologics, Center for Devices and Radiological Health, and Center for Veterinary Medicine.

products.[3] Since detained products cannot be moved during the detention period, this authority would help FDA prevent potentially violative products from getting on the market while recommended legal actions are approved and implemented. The Congress has not yet acted to give FDA this authority.

FDA already has detention authority over imported products (including foods), medical devices, and certain meat, poultry, and egg products. Products in the latter four categories can be detained for up to 20 days, and for medical devices, the detention period can be extended to 30 days if a seizure action or injunction is expected. Imported products can be detained as long as necessary for FDA to complete its regulatory action. Our September 1984 report pointed out that some FDA headquarters and district office officials believed that any detention authority provided FDA for food products should be for 30 days. Officials from two food associations agreed that FDA needs detention authority provided that it is limited to 30 days.

The September 1984 report also pointed out that the implementation process for the seizure actions reviewed averaged 65 days, of which 41 days were attributable to FDA's collection, testing, and review process. Of this time, district offices took an average of 24 days. Although we believed that laboratories were using most of the district office time, we did not know why.

The Sample Process

FDA's 22 district offices perform the bulk of its field activities. Each office is headed by a district director, who is responsible for operations Generally, district office operations are divided into four branches: investigations, laboratory, compliance, and administrative management.

Seventeen of the 22 districts have a laboratory branch. Sample testing for the other five districts is carried out by two regional laboratories (see app. I). The 19 laboratories have staffs totaling about 650 people. The cost to operate these laboratories during fiscal years 1984 and 1985 was about $34 million and $31 million, respectively.

The sample review process begins when an investigator from a district office investigations branch collects a sample for laboratory analysis as the result of an establishment inspection, a wharf examination, a

[3] Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (HRD-84-61, Sept 26, 1984)

product sampling program, or a consumer complaint. The investigator prepares a collection report, which describes the sample and tells where and why it was collected. The investigator either carries or ships the sample and collection report to the FDA laboratory responsible for testing it. At the laboratory, the sample is placed in a locked storage area and entered in the laboratory's sample inventory.

After receiving the collection report, a laboratory manager places a priority on the sample and assigns it to an appropriate analyst (either a chemist, a microbiologist, or a biologist/entomologist). The analyst tests the sample using a prescribed method and prepares a written report on an analyst work sheet. The 14-section analyst work sheet/report, along with continuation sheets, provides an extensive and detailed account of sample testing

When testing has been completed, a laboratory supervisor checks the information recorded in the written report for testing method suitability, accuracy of calculations, overall accuracy, and completeness and determines whether the sample is in compliance with the laws and regulations enforced by FDA. If the supervisor concludes that the sample is violative, the information is referred to the district compliance branch, which reviews it along with other available evidence concerning the product or the firm. If the compliance branch believes regulatory action is needed, it recommends to appropriate headquarters officials the most suitable course of action.

FDA investigators classify samples they collect into two major categories—compliance samples and surveillance samples. The former are samples that FDA believes have a high likelihood of being violative, are generally collected in conjunction with an establishment inspection, are used to support a regulatory action, and have a higher testing priority than surveillance samples. The latter are samples that FDA tests to obtain safety and other data about selected products from a local or national perspective. Surveillance samples found to be violative are sometimes used to support regulatory actions or further investigational effort.

To track samples through the laboratory—from receipt to final disposition—laboratory directors use a computer-based laboratory management system. The system contains information on the sample inventory, work-in-process, and sample output which is summarized weekly for each laboratory director.

Objective, Scope, and Methodology

The objective of this review was to determine whether improved management of sample processing by field laboratories could improve FDA's regulatory efforts to prevent or remove violative products from the market. The review focused on the time FDA's laboratories take to process product samples, the impact delays had on FDA's ability to take appropriate regulatory action on products found to be violative, and measures that can improve the timeliness of laboratory sample processing. We made this review because of the long time it took FDA district offices to process samples associated with seizure cases as reported in our September 1984 report.

The review was performed at FDA headquarters in Rockville, Maryland; at the Atlanta, Detroit, and New Orleans district offices; and at the Atlanta regional laboratory, which serves the Atlanta, Nashville, and Orlando districts. The Atlanta, Detroit, and New Orleans laboratories were selected because of the number of samples they tested and the differences in their average sample processing times. The three laboratories processed 14,839 of the 82,491 samples (18 percent) included in the laboratory management system data base discussed below. We performed limited work initially at the Boston, Buffalo, and Dallas district offices to obtain insights into the processing of samples and the reporting of test results. We also reviewed documentation concerning the Los Angeles district office's pesticide work

To provide a national perspective on the timeliness of sample processing and to show the wide variations in processing time among the laboratories, we obtained and analyzed laboratory management system data on 82,491 samples processed by 19 of FDA's field laboratories during fiscal year 1984 and the first 6 months of fiscal year 1985. Information we obtained from the laboratory management system for each sample included (1) the sample classification (compliance or surveillance), (2) the date the sample was collected, (3) the date the sample was entered into the inventory, (4) the date the sample was assigned to a laboratory analyst, (5) the dates that sample testing and the supporting report were completed, and (6) the date that sample review was completed and a report left the laboratory. We also obtained data on whether the product sample was violative. For each sample we determined the amount of laboratory time—that is, the total time required by the laboratory to complete the testing and supporting report and to report the results out of the laboratory and the amount of time the sample spent in the inventory waiting to be tested.

We excluded data on 19,638 samples from the laboratory management system data base About 14,250 samples related to FDA's total diet work; they were collected by FDA to obtain trend information about residues in the American consumer's diet, and regulatory action was not contemplated. In addition, data on about 4,780 samples were excluded because the data were obtained from three state-operated pesticide surveillance programs and were not part of FDA's actual workload. Data for the remaining 608 samples were excluded because these samples were generally used in small, nonregulatory projects, such as quality assurance tests, and to confirm testing methodologies suggested by drug firms for new products.

We made a limited assessment of the laboratory management system data to determine whether they were accurate. Our assessment consisted of reviewing the accuracy of the data input into the system for eight variables on 75 samples selected at random from one district laboratory's fiscal year 1984 data base. Five of the variables involved dates associated with the samples, such as the collection dates and the dates the samples were available to the laboratory for testing (see p. 11). The other three variables involved codes that identified what the samples' program area was, whether they were compliance or surveillance samples, and whether the testing showed them to be violative.

We traced data from FDA's original documents and records to the data contained in the laboratory management system. Based on the results of our work, we have no reason to believe that using the computerized data would overstate the district office's average sample processing times. Our review revealed an error rate of 6.5 percent (39 errors for the 600 variables checked). Most of the 39 errors involved dates and tended to understate sample processing time. Specifically, 33 of the 39 errors involved the five dates associated with sample processing. Of the 33 date errors, 27 understated the laboratory sample processing time.

To gain insights into how samples flow through the laboratories, to identify why sample processing is often delayed, and to show the impact of delays, we reviewed files on 114 of 1,577 violative product samples identified in fiscal year 1984 by three laboratories where we conducted our detailed work. The 114 cases selected were those with the longer processing times in each field laboratory.

We reviewed the agency's policies and procedures concerning sample processing and FDA's use of time-frame guidelines to ensure timeliness.

In addition, we asked FDA's Acting Director, Office of Regional Operations, to respond to specific questions regarding (1) sample processing, (2) the need for timeliness, and (3) the system used by field laboratories to set priorities for sample testing. We reviewed FDA's policies and procedures pertaining to paperwork requirements for reporting sample test results by field laboratory analysts. We also reviewed selected field laboratory quality assurance reports and their supporting documentation. We did not assess the quality of sample testing by individual analysts or the time they took to complete specific analyses (bench time). Rather we focused on other factors that collectively determine the time needed by field laboratories to report sample test results. The Department of Health and Human Services (HHS) has stated that the analyses performed by FDA's laboratories are of high quality as evidenced by their acceptance in the courts, in public hearings, and by the scientific community.

To compare and show how other agency laboratories manage their sample processing, we met with officials of the U.S. Department of Agriculture, Food Safety and Inspection Service, Field Service Laboratories Division, in Washington, D.C., and the Michigan Department of Agriculture Laboratory Division in East Lansing. These two agencies do some work that is similar to that done by FDA's field laboratories.

Our review was made in accordance with generally accepted government auditing standards with the following exception. We reviewed the accuracy of the automated laboratory management system at only one district office because of time limitations and because the data errors found at this office tended to understate the laboratory's sample processing time. Our work was performed between June 1985 and January 1986.

FDA Should Establish Sample Processing Time Frames for Field Laboratories

To achieve its consumer protection responsibilities, FDA must quickly identify and remove known or suspected violative products from the market. Because FDA usually relies on laboratory testing to identify violative products, its field laboratories must process product samples in a timely manner. Timely processing also avoids possible economic losses both for importers, whose products are sometimes detained by FDA pending sample testing, and for domestic establishments, which sometimes voluntarily hold suspected violative products or whose products are detained for FDA by state or local agencies.

Despite the importance of timely laboratory product sample processing, untimely processing is a problem for FDA. Our analysis of 82,491 samples that field laboratories tested during the 18 months ended March 31, 1985, showed that the laboratories took an average of 28.4 calendar days from receipt of the sample to reporting the test results. For individual laboratories, the time ranged from 8.5 to 87.6 calendar days. Although FDA has recognized this problem, it has not established sample processing time frames against which it can evaluate its laboratories' effectiveness in processing all types of samples.

Untimely Sample Processing Continues to Be a Problem

We stated in prior reports[1] that the faster FDA acts, the greater its success in keeping or removing violative products from the market. These reports showed that a lack of timeliness was a major shortcoming in the FDA regulatory process. As a result, by the time FDA completed its laboratory processing and other requirements necessary to take action against violative food and drug products, the products were often further distributed and could not be located

Our prior reports concluded that greater amounts of violative products could be kept or removed from the market if FDA were given broader detention authority over the products it regulates. As discussed on page 9 of this report, a 30-day detention period was considered reasonable by both FDA and some food industry officials to determine whether a product is violative and, if so, to take appropriate regulatory action.

In a current review of pesticide residues in foods, we found that FDA was not able to prevent many violative products from reaching the consumer because of untimely laboratory processing. By the time FDA identified

[1] Lack of Authority Limits Consumer Protection Problems in Identifying and Removing From the Market Products Which Violate the Law (B-164031(2), Sept 14, 1972), Legislative and Administrative Changes Needed to Improve Regulation of Drug Industry (GAO/HRD-83-24, Apr 5, 1983), and the report listed in footnote 3 on page 9

the products as violative, they were often no longer available because most agricultural products are perishable and therefore move rapidly from farms to consumers.

During the review covered by this report, we also found FDA's field laboratories to be untimely in processing product samples. We analyzed the processing time for 82,491 samples that FDA's field laboratories tested in fiscal year 1984 and the first 6 months of 1985. This analysis showed that during this 18-month period, the laboratories took an average of 28.4 calendar days from receipt of the sample to reporting the analytical results. Processing time for all samples and for domestic and import samples by fiscal year is shown in table 2.1. The performance of individual laboratories varied widely (see app. II).

Table 2.1: Average Processing Time for Various Sample Categories

	Fiscal year 1984		First 6 months of fiscal year 1985	
Category	No. of samples	Average no. of calendar days	No. of samples	Average no. of calendar days
Domestic samples	32,556	36 7	19,610	42 9
Import samples	16,787	10 3	13,538	10 1
All samples	**49,343**	**27.7**	**33,148**	**29.5**

Appendix III shows that in fiscal year 1984 and the first 6 months of 1985, the laboratories took more time (32.5 and 38.3 calendar days, respectively) to process surveillance samples, but less time to process compliance samples. Import compliance samples were in the laboratories an average of about 11 calendar days in both periods, while domestic compliance samples were in the laboratories an average of 20 and 29 calendar days, respectively.

Our review of case files for the violative product samples identified by three laboratories during fiscal year 1984 revealed the following instances where delays in laboratory sample processing resulted in violative products reaching the market.

1. On August 24, 1983, a consumer complained to FDA about adulterated olive oil because she suspected that it had been diluted with other oils. The sample FDA collected was available for laboratory processing on August 26, but testing was not immediately begun. The district laboratory terminated its work on the sample on January 31, 1984 (about 5 months later), when it learned from another district that the product

was being recalled from the market by the importer because it was adulterated with animal fat. The recall was initiated on December 8, 1983. The circumstances leading to the recall involved an August 15, 1983, consumer complaint regarding product quality. Analysis of a sample in another district's laboratory resulting from the August 15 consumer complaint was not completed until October 28, 1983. The recall recovered only 576 gallons (or less than 10 percent) of 5,868 gallons of the adulterated oil.

2. On January 30, 1984, FDA collected a sample from a grain elevator containing about 26 tons of bulk shelled corn intended for animal feed. The laboratory received the sample on February 1. Laboratory tests completed on March 29, 1984 (about 2 months later), showed that the product was contaminated with aflatoxin, a potent carcinogen. Aflatoxins in feed can transfer to milk and edible tissues of exposed animals. When the field investigator checked on the availability of the product for a regulatory action, FDA found that all 26 tons had been distributed. FDA took no further action because it assumed the corn could not be recovered.

FDA Has Time-Frame Guidelines for Some Samples, but Opposes Them for Others

During the middle to late 1970's, FDA established sample processing time frames because it recognized that time lags added to consumer costs, limited the protection provided to the consumer, precluded timely legal actions, and interfered with the flow of foreign goods into the United States. These time frames covered three groups of samples: those associated with (1) import compliance samples, (2) domestic compliance samples, and (3) samples of products where legal actions were to be taken.

Import sample time frames established in April 1977 represent maximum times that should be required for field offices to process import samples. As shown in appendix IV, these include specific time frames for the laboratory and other district office branches and for the various types of tests that the laboratories perform. These time frames have remained in effect since then. However, in a December 1985 response to our inquiry on the need for timeliness, the Acting Director, Office of Regional Operations, told us that FDA was reviewing the import time frames because of FDA's concern that the increased volume of import samples could cause an undue burden on some laboratories. As of September 1986, these time frames were still under review.

Domestic sample time frames, implemented in March 1979, established a maximum laboratory processing time of 10 days for domestic compliance samples. This criterion was superseded in April 1984, when a procedures manual revision supplanted it. According to an FDA headquarters official, the criterion was superseded to conform the procedures manual with the June 1981 legal action time frames discussed below.

Legal action time-frame guidelines were started in January 1975 as a test program and formalized in May 1978. The system specified workday limits for field and headquarters processing of regulatory actions. Unlike the import and domestic compliance sample time-frame guidelines that specified times for laboratory processing, the legal action guidelines prescribed district office times.

FDA terminated this system in June 1981 because it received some reports that field offices might have been compromising the quality of their work to meet the time frames. In its place, FDA established a revised legal action time-frame guideline system with less rigorous suggested time frames. For example, the 1978 guidelines specified that district offices had 13 workdays to complete their part of processing seizure cases; the June 1981 guidance suggested that this work should be completed in 20 workdays. FDA does not know how the change to the less rigorous time-frame guidelines affected its regulatory effectiveness in dealing with violative products, because it does not monitor field laboratory performance in meeting the guidelines. (See p. 20.)

FDA Opposes Time-Frame Guidelines for All Import and Domestic Samples

In the December 1985 response letter to GAO, the Acting Director, Office of Regional Operations, reiterated FDA's June 1981 position that the quality of testing takes precedence over timeliness and strict time frames for sample processing could lead to the quality of sample testing being compromised. In addition, the FDA letter cited differences among the laboratories, such as the import workloads and emergency and recall situations, as reasons why time frames could not be used to evaluate the timeliness of sample processing. In regard to time frames for surveillance samples, the letter stated that many "are low in priority and prompt completion is not required . . ."

While the import workload does vary among laboratories and emergency and recall situations do occur, these factors have not resulted in untimely sample processing at some laboratories. For example, our evaluation of FDA's laboratory management system data on the samples

tested by the 19 field laboratories during the 18-month period showed that 4 laboratories processed all their samples in an average of about 10 workdays or less (see table 2.2). The four laboratories' workload represented over 36 percent of the 82,491 samples. Furthermore, many of the samples required the more time-consuming microbiological analyses.

Table 2.2: Average Processing Time for Samples Tested by Four Laboratories

Laboratory	No. of samples	Average no. of workdays
Dallas	8,971	9 2
New York Import	5,264	6 8
San Francisco	9,035	9 0
Seattle	6,506	10 4

Moreover, while import workloads vary by laboratory, laboratories with the greatest import workloads often were the most timely in their sample processing (see app. V). Of special note are the Dallas and New York Import laboratories' timely performance on a large number of samples during the 18-month period we evaluated. The Dallas laboratory processed 4,692 import samples in an average of 3.2 workdays; the New York Import laboratory, with a workload that is over 90 percent import samples, processed 4,845 import samples in an average of 6.5 workdays.

We recognize that emergency or recall situations are a fact of life for FDA. They can result in a large influx of samples to the laboratory in a short period and delay the processing of other samples. In an emergency, some samples already in inventory may not be processed in a timely manner. FDA's inventory controls should assure that additional surveillance samples are not added to the inventory until the crisis is over. Problems in managing laboratory sample inventories are discussed in more detail in chapter 3.

Processing of Surveillance Samples Should Be Subject to Time-Frame Guidelines

As indicated by its efforts to establish some kind of sample processing guidelines, FDA gives a higher priority to compliance samples because they are collected based on a likelihood of their being violative. Although surveillance samples were considered to have a lower priority, they accounted for about half of the 82,491 samples included in the 18-month laboratory management system data base, and they represented about 26 percent (3,266) of the 12,426 violative compliance and surveillance samples. However, if surveillance samples are not processed in a timely manner, FDA may be precluded from taking any regulatory action

on a violative product because it is no longer available, or any action taken may be of limited success.[2] For example:

1. On November 1, 1984, FDA collected a surveillance sample from 1.6 tons of caviar processed by a domestic firm. Laboratory testing of this sample completed on January 2, 1985 (2 months later), showed that the product was contaminated with excessive amounts of polychlorinated biphenyls, a toxic industrial chemical. When the field investigator checked on the availability of the product for a seizure action on January 8, the investigator found that none was available. FDA took no action because it assumed that the product had entered the market and been consumed.

2. On March 20, 1984, FDA, as part of its aflatoxin surveillance program, collected a sample from about 40,000 pounds of peanut butter packed in 80,928 jars of various sizes. Laboratory testing completed on May 23, 1984 (2 months later) showed that the peanut butter was contaminated with aflatoxin, a potent carcinogen. The manufacturer agreed to recall the peanut butter, which had been distributed in March and April. The recall, initiated on May 30, recovered only 10,517 of the 80,928 jars because the product was out of stock at most retail stores.

The need for timely processing of surveillance samples is equally important for imported sample products normally not held by FDA pending sample processing. Without timely processing, the sampled products may not be available for regulatory action, should they be identified as violative. For example:

3. On November 30, 1983, FDA collected a sample from 4,465 pints of Chilean strawberries from an importer. FDA let the strawberries enter the country at the time it sampled them. Although the laboratory received the sample on December 5, testing was not completed until February 13, 1984 (over 2 months later). Test results showed that the strawberries were contaminated with excessive amounts of chlorothalonil, an unsafe pesticide chemical. Although FDA's "may proceed" release does not preclude action should the merchandise later be found violative, in this case FDA took no action because it assumed that after 2-1/2 months, there were no strawberries left to act on.

[2]In fiscal year 1984 and the first 6 months of fiscal year 1985, the field laboratories took 32 5 and 44 3 calendar days, respectively, to process surveillance samples.

FDA recognized the problem of untimely surveillance sample testing in an August 1983 internal study Assuring Adequate Coverage of the Food Supply for Chemical Residues. The study reported that in the first 5 months of fiscal year 1983, violative surveillance samples took an average of 28 calendar days between the date of collection and the date sample review was completed and a report left the laboratory. (We found that for the first 6 months of fiscal year 1985, violative domestic pesticide surveillance samples took an average of 27.3 calendar days for the same process.) The study recommended that FDA give its districts more workable guidance on time frames for completing sample testing. An FDA headquarters official told us that no action has been taken on this recommendation because FDA believes its district offices must set their own timeliness criteria according to their circumstances.

FDA Headquarters Does Not Monitor or Evaluate Laboratory Performance Against Time-Frame Criteria

FDA headquarters performed some time-frame studies before revising the legal action time-frame guidelines in 1981. However, it does not currently carry out any monitoring or evaluation of whether its field offices are meeting the established sample processing time frames, nor has it established procedures for assessing the appropriateness of the time frames. FDA headquarters officials believe that field office quality assurance reviews give FDA management assurance that field activities (including laboratory sample processing) are being carried out in accordance with established guidelines. In the December 1985 response letter to GAO, the Acting Director, Office of Regional Operations, said that semiannual quality assurance program reports they receive from the field offices indicate that the number of samples processed by field laboratories that exceed established time frames is not a serious problem. Our review indicated, as discussed below, that FDA's field laboratories show a high rate of noncompliance with the time-frame guidelines.

Directors of two laboratories we visited did not use the import and legal action time-frame guidelines to assess the timeliness of their sample processing. The directors were applying their own informal criteria to evaluate the timeliness of their laboratory's work. As a result, they did not report any problems with meeting time frames on their quality assurance program reports submitted to FDA headquarters. For example, one director reported that he reviewed 62 analyst work sheets for fiscal year 1984 and found no time-frame defects. We reviewed the laboratory management system sample data associated with these 62 work sheets and found that only 19 involved samples that were subject to established time-frame guidelines. Of these 19 samples, the laboratory did not meet the time frames for 6

In addition, many import compliance samples processed by the field laboratories did not meet time-frame guidelines. Our analysis of individual processing times for 12,501 non-microbiological import compliance samples tested by the 19 field laboratories in the 18-month period ended March 31, 1985, compared to the established time frames, showed that processing time for 8,040 samples, or 64 percent, exceeded the guidelines. For individual laboratories the range was from 23 to 98 percent. Furthermore, 14 of the laboratories exceeded the guidelines for 50 percent of the samples.

Time-Frame Guidelines Should Correspond to Laboratory Priorities to Facilitate Monitoring and Evaluation

FDA currently identifies all samples as either compliance samples (priority) or surveillance samples (nonpriority). The investigators (who collect the samples) make these formal designations, which are used to identify samples in the laboratory management system data base. FDA field laboratories, however, do not use the compliance/surveillance designators to schedule the testing of samples because they often are not relevant to the samples' processing priority. Instead, the laboratories assign priorities to the samples (with input from the investigations branch) using a more refined system of priority categories. The laboratories place samples into four categories (top priority, high priority, routine 1 priority, and routine 2 priority). For example, the laboratory branches could informally assign a priority to a consumer complaint sample as follows. If the sample related to a complaint involving death or injury, it would have a "top priority" designation; if it related to a complaint involving a potential health hazard, it would have a "high priority" designation; and if it related to a complaint involving a nonhealth hazard, it would have a "routine 1 priority" designation.

In contrast, the collecting investigators would formally identify the above sample as a compliance (priority) sample, and this designator would be associated with the sample in the laboratory management system data base. As a result, when attempting to assess the timeliness of laboratory processing for the sample, the evaluation breaks down because the "compliance" priority identification may not tie in with the priority designation used by the laboratory processing the sample.

Therefore, FDA laboratory processing time-frame guidelines should be integrated with laboratory sample processing priorities. Furthermore, if FDA were to add the laboratory processing priority designations to the laboratory management system data input, FDA management would have greater monitoring capability over laboratory performance.

Conclusions

In view of the many violative products identified through the testing of surveillance samples, it is important that these samples have timely processing goals. In our opinion, surveillance samples that are violative warrant the same regulatory attention that FDA gives to violative compliance samples. We share FDA's belief that high-quality sample testing must be maintained and should not be compromised to meet time-frame goals. We also believe, however, that timeliness is an important factor in quality testing and that it is possible to set specific time-frame goals that will not compromise the quality of FDA's work and should improve its effectiveness. Therefore, FDA should develop a system of time-frame guidelines for processing all laboratory samples. Such a system should set reasonable sample processing time frames that would include time to adequately test the samples.

In addition to promoting maximum consumer protection, insuring timely legal actions, and minimizing interference with the flow of foreign goods into the United States, other factors support the need for sample processing time frames. We believe that such criteria are an essential management tool to aid in setting priorities, identifying potential problems, adjusting resources, and providing goals for improving and measuring laboratory performance. Setting time frames should also sensitize district offices to the importance of timely sample processing. Moreover, if broader detention authority is given to FDA, laboratory sample processing must be completed in a timely manner to allow review and implementation of regulatory actions within the allotted period.

FDA headquarters does not monitor or evaluate field performance in meeting established laboratory processing time-frame guidelines. Such oversight is needed to determine whether field performance meets FDA headquarters expectations. Furthermore, the compliance and surveillance priority designators now used by FDA are not conducive to evaluating laboratory sample processing performance because they are not consistent with the priority categories the laboratories use in scheduling samples for testing. FDA should develop and implement sample processing guidelines that are consistent with the field laboratories' priority designators.

Recommendations to the Secretary of HHS

We recommend that the Secretary direct the Commissioner of FDA to

- establish time-frame guidelines for field laboratories' processing of all samples consistent with the four sample processing priority designators used by the laboratories,

- change the laboratory management system sample priority classifications to those used by the laboratories in setting processing priorities to (1) enable laboratory managers to better schedule the testing of samples and (2) give laboratory managers greater monitoring capability over laboratory performance, and
- evaluate field laboratory performance in meeting the time-frame guidelines.

Agency Comments and Our Evaluation

In a letter dated August 8, 1986, HHS commented on a draft of this report. (See app. VII.) HHS agreed with our recommendations and stated that, as a result of our work, FDA will appoint a task force composed of laboratory directors and other appropriate personnel to review this report, study field laboratory management, and propose policies and practices to enhance laboratory operations. One aspect of the task force's charge will be to examine sample processing time frames and priorities and recommend a workable priority system with appropriate time-frame guidelines.

The task force will also develop implementation and monitoring instructions that provide for laboratory accountability while recognizing that laboratory management is the responsibility of FDA's district directors. The task force will also assess the computerized laboratory management system and make recommendations commensurate with its overall study.

HHS also agreed to require FDA to establish evaluation and monitoring procedures for headquarters units to assess the laboratories' performance in meeting the established sample processing time-frame guidelines.

We believe that if implemented, these proposed actions will enhance FDA's ability to keep and remove violative products from the market, thus increasing the protection of consumers. FDA's actions will also provide much needed headquarters oversight of field laboratory activities.

Laboratory Directors Need to Better Manage the Sample Inventory

Product samples collected by district investigators spend a long time in the inventory waiting to be tested. For 82,491 samples we reviewed, about 50 percent of the average laboratory processing time (13.3 of the 28.4 calendar days) was inventory time—the time a sample was waiting to be tested. This delay often causes the testing of the sample to be untimely and hampers FDA's efforts to take regulatory action against violative products.

Samples spend such a long time in the inventory primarily because the flow of samples into the inventory and the size of the inventory have not been adequately controlled by laboratory directors. While compliance samples are much less controllable in view of their likelihood of being violative, the collection of surveillance samples can be controlled. Although the directors have developed some techniques to help control the inventory, they have not always been effective.

Samples Remained in Inventory a Long Time

The laboratory management system data for the 18-month period ended March 31, 1985, showed that samples were in the inventory waiting to be tested for an average 13.3 calendar days. The data also showed that some field laboratories had much lower inventory times than others. For example, during the 18-month period, the samples tested by one laboratory averaged 2.9 calendar days in the inventory while samples tested by another laboratory averaged 48.6 calendar days. Appendix VI shows the average time that samples were in the inventory at each laboratory for fiscal year 1984 and for the first 6 months of fiscal year 1985.

The inventory at some laboratories we visited consisted primarily of surveillance samples, and the size of the inventory precluded the timely processing of many samples. For example:

1. At one laboratory, we found that on September 12, 1985, the samples in the inventory consisted of 146 surveillance samples and 3 compliance samples. This represented about 7 weeks' work, based on the average number of samples the laboratory processed per week over a 1-year period. On the average, samples at this laboratory remained in the inventory for 56 6 calendar days during the first half of fiscal year 1985.

2. At another laboratory, records showed that there were 153 surveillance samples in the inventory waiting to be analyzed for aflatoxin at one point during fiscal year 1984. (Aflatoxins are considered potent carcinogens by FDA) Samples analyzed for aflatoxin at this laboratory

remained in the inventory for an average of 48.3 calendar days during fiscal year 1984. The impact that such delays can have on FDA's regulatory actions is illustrated on pages 15 and 16.

In one district, the district director monitored the amount of time it took other field laboratories to process samples received from the district. Records at the district laboratory showed that, on December 21, 1984, 106 samples (76 percent of which were surveillance samples) were waiting analysis at other field laboratories. Our review of the records showed that 81 of the samples had been in the inventory of other laboratories for over 30 calendar days; moreover, 58 of the 81 samples had been in the inventories for over 200 days.

FDA Officials Believe Sample Inventory Size Cannot Be Controlled

FDA officials have recognized the need to better control the size of the inventory if samples are to be timely tested. However, FDA headquarters has not given its field laboratories guidance on how to manage the inventory size. According to the Acting Director, Office of Regional Operations, guidance has not been provided because FDA cannot control when suspected violative products will be identified or how many product samples will be collected for testing.

Most field laboratory directors we talked with also believed that the inventory size could not be controlled because techniques they use have not worked. These techniques had not been formalized by FDA, and their effectiveness in helping laboratory directors control the inventory size varied by laboratory

The field laboratory directors told us that the inventory size cannot be controlled because (1) they cannot control the rate at which samples are received from their own district's investigations branch and (2) the flow of samples received from other districts is not coordinated with their laboratory's ability to analyze them.

Procedures Are Needed to Improve Control of Inventory Levels

We recognize that samples of potentially violative products should be collected by investigators when they are identified, and the flow of these samples into the inventory cannot be controlled. Potentially violative samples, classified as compliance samples by FDA, include both import and domestic samples and represented at least one-third of the 82,491 samples in the laboratory management system data base during the period October 1, 1983, through March 31, 1985.

Although the number of compliance samples collected is less subject to control, the collection of surveillance samples can be controlled. Control of these samples, which represent about one-half[1] of the workload, is the key to controlling the inventory. Controlling the receipt of surveillance samples involves better using some techniques that are now being used by the laboratories we visited. These techniques include (1) meetings between the laboratories and investigations branches to coordinate the flow of surveillance samples into the inventory; (2) procedures to prohibit the collection and delivery to the laboratories of large numbers of samples in order to meet collection quotas (dumping); (3) scheduling the receipt of surveillance samples received from other districts; and (4) having each laboratory director determine an appropriate size for the inventory based on the laboratory's ability to timely test the samples.

Better Coordination Between Investigations and Laboratory Branches Needed in Collecting Surveillance Samples

According to officials at two laboratories we visited, they have coordination meetings with the investigations branch in their district concerning the collection and flow of samples into the inventory. The frequency of the meetings varied, as did the results.

At one laboratory, the meetings were not successful in controlling the flow of samples into the inventory because the investigations branch considered the information to be merely advisory. Investigators in this branch continued to collect the samples needed to meet branch requirements, including dumping samples into the inventory, without giving adequate consideration to the laboratory's ability to timely test the samples.

When such dumping occurs, all the samples cannot be timely analyzed. For example, the director at this laboratory stated that the investigations branch overloaded the laboratory during the latter part of fiscal year 1985 by dumping samples to be tested for pesticides into the inventory. These samples were collected to meet the investigations branch sample collection requirements for its pesticide program. Ultimately, the director disposed of about 50 of the samples without testing them because he decided that they had no significant analytical value. Surveillance samples at this laboratory remained in the inventory for an average of 58.6 calendar days during fiscal year 1984. The director at

[1]During fiscal year 1984 about 12,830 samples, or about 16 percent of the 82,491 samples in the laboratory management system data base, were not classified by FDA as either compliance or surveillance

this laboratory stated that laboratory supervisors could not control the rate of sample collection by the district.

At the second laboratory, where the laboratory director believed that inventory control was part of his responsibility, the inventory was better controlled. Surveillance samples at this laboratory remained in the inventory an average of 6.7 calendar days during fiscal year 1984. The director at this laboratory told us that all field laboratory directors must take an active role in determining the flow of samples into their laboratory's inventory. He said that the flow of samples into the inventory and the size of the inventory have a significant impact on the time that samples spend in the inventory. According to the director, investigators should not be permitted to overload the inventory because of their sample collection process. He added that the rate at which samples enter the inventory must be well coordinated between the investigations branch and the laboratory. Investigators must understand that they cannot "dump" samples into the inventory.

At one laboratory where coordination meetings did not take place, a laboratory supervisor told us that lack of coordination between the investigations branch and the laboratory was a major reason why it was difficult to control the inventory. For example, the supervisor told us that he requested the district's investigations branch to temporarily reduce the number of surveillance samples being collected because of a backlog of samples in the inventory. According to the supervisor, the investigations branch ignored his request. As a result, the laboratory continued to receive samples that were not always timely processed.

Although the director of this laboratory stated that surveillance samples collected by investigators could be controlled through coordination meetings, he believed his laboratory was at the mercy of the investigators in controlling the rate at which samples enter the inventory. During fiscal year 1984, surveillance samples at this laboratory remained in the inventory an average of 29.7 calendar days.

The laboratories we visited did schedule the receipt of some surveillance samples received from other districts. However, these schedules were not always followed. For example, one director stated that it was not uncommon for his laboratory to receive samples sent from other districts near the end of the fiscal year, rather than throughout the year in some orderly fashion. The director said that, as a result, these samples sometimes overloaded the laboratory.

Laboratory Directors Should Determine an Appropriate Inventory Level

An important part in controlling the size of the sample inventory is determining its appropriate size. If the inventory is too large, as it was at two of the laboratories we visited, samples will not be timely analyzed. If the inventory is too small, laboratory personnel may be without samples to test.

Although laboratory officials told us that there is no FDA or field criteria relating to inventory size, some of them had an idea of an appropriate inventory size. The director at one laboratory told us that the sample inventory should represent a reasonable workload and that a 2 months' backlog was reasonable. At another laboratory a supervisor said that 1 week's work for each analyst was about the right size. At a third laboratory, the director told us that he had established an inventory size of about 300 samples, which he believed represented about 1 week's work. He established the ceiling because he did not want samples sitting in the inventory getting old.

Some Laboratories Control Their Sample Inventories

To obtain sample processing information from laboratories that perform many sample analyses, we contacted officials at the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), Field Service Laboratories Division, and the Michigan Department of Agriculture Laboratory Division. As part of their role, the FSIS laboratories test meat and poultry tissue samples for spoilage, adulteration, or prohibited contaminants. The Michigan laboratory performs, among other functions, chemical, microbiological, and pesticide tests of food, dairy, and beverage products.

According to the director of the FSIS Field Service Laboratories Division, neither a standard relating to inventory size nor procedures specifying laboratory and inspection branch coordination have been established. However, FSIS's analytical work plan provides monthly schedules of the numbers and types of samples to be collected for the field laboratories. The schedules are based on historical laboratory performance and changes in the laboratories' testing capabilities.

In addition to the assessment and distribution of work, the director stated that laboratory managers use a computer tracking system to manage their workload. The system maintains data on sample flow and identifies samples received, tested, discarded, and remaining in backlog. According to the director, FSIS has a system that permits FSIS management to monitor and help control inventory size at its laboratories.

Officials at the Michigan laboratory told us that normally they do not have problems with inventory overload. The officials stated that samples are received daily and laboratory supervisors receive a weekly report that identifies the age of each sample in the inventory. The officials said that an inventory overload could occur in an emergency situation, such as a large food poisoning outbreak. However, if this were to happen, the officials said that laboratory supervisors would ask division inspectors to slow down or even temporarily stop sample collection.

The state officials also told us that some product samples, such as milk and cheese, are collected on a specific schedule, so that the laboratory receives them on a consistent, regular basis. In this instance, the laboratory has a receipt schedule that was coordinated with inspectors in the Michigan Department of Agriculture Dairy Division. According to the officials, the laboratory's sample processing capability is considered when the sampling schedule is developed, and the state does not plan to collect more samples than can be timely tested by the laboratory.

In addition, the officials told us that although a specific inventory size has not been determined, if the inventory represented more than 2 or 3 weeks' work, action would be taken to reduce it. If this occurred, they would ask inspectors to reduce their sample collection.

The director at one FDA laboratory did more to control the sample inventory than officials at the two other laboratories we visited. The results of this effort were reflected in the relatively short period samples remained in the inventory. For example, the laboratory management system data for the first 6 months of fiscal year 1985 showed that samples at this laboratory remained in the inventory an average of 5.4 calendar days and the national average for all 19 field laboratories was 14.5 calendar days. In contrast, the average inventory time for the other two laboratories was 27.0 and 56.6 calendar days. The director at this laboratory said that day-to-day management of the inventory was handled by laboratory supervisors. These supervisors monitored the inventory weekly and used informal coordination meetings with the investigations branches to keep the inventory under control. This laboratory has established an inventory size representing about 1 week's work.

Conclusions

Samples collected by FDA spend a long time in the inventory waiting to be tested because laboratory directors have not adequately controlled inventory levels. To more effectively control the inventory, laboratory

directors must have greater inputs into determining the flow of samples into their laboratory's inventory and in controlling the size of the inventory. Laboratory directors can improve their control over the flow of samples through regularly held coordination meetings with the investigations branch. One FDA laboratory we visited has used such meetings with great success.

The purpose of the meetings is to inform the investigations branch of the laboratory's workload and to coordinate the collection of surveillance samples. Coordinating surveillance sample collection is necessary to preclude the inventory from becoming overloaded. Surveillance samples should be collected taking into account such factors as the laboratory's capability to test samples, the number of samples in the inventory and the workload they represent, and the flow of compliance samples into the inventory.

Laboratory directors should continue to provide district directors sending surveillance samples to the laboratory a schedule showing when the samples should be received. District directors and investigations branch chiefs in these districts should follow the schedules to prevent overloading the laboratory's inventory. Adjustments to the schedule should be agreed to by the laboratory director. If the laboratory's inventory should become overloaded because of unanticipated higher priority work, the laboratory director could revise the schedule to reflect the impact of the unanticipated work. In some instances, fewer surveillance samples than planned may be tested because of the greater number of higher priority samples.

To control the flow of samples into the inventory, laboratory directors need to know when their inventory reaches a reasonable size. This requires them to know what samples are in the inventory and the amount of work they represent and to have some idea as to the number of samples the inventory should contain. Because some tests take longer than others, the number of samples cannot be used as the sole criterion.

Recommendations to the Secretary of HHS

We recommend that the Secretary direct the Commissioner of FDA to establish procedures that require

- district offices' investigations and laboratory branches to coordinate and schedule the collection of surveillance samples;

- the investigations branch to collect surveillance samples in accordance with the collection schedule developed with the laboratory branch, unless an emergency should arise;
- laboratory directors to continue to prepare schedules for receipt of surveillance samples tested for other districts and require these districts to follow the prepared schedules, unless agreements on deviations from the schedules are reached with the laboratory; and
- laboratory directors to determine an approximate inventory size that will permit the processing of samples within the time-frame guidelines established by FDA.

We also recommend that the Secretary direct the Commissioner to establish a policy that prohibits the "dumping" of product samples into a laboratory's inventory.

Agency Comments and Our Evaluation

In its August 8, 1986, letter, HHS stated that many of FDA's district directors currently hold informal meetings with branch directors to plan their work schedules. (See app. VII.) Inspections scheduling, collection of surveillance samples, and laboratory backlogs are discussed at these meetings. HHS recognized that there are exceptions to this management practice among the district directors and said steps will be taken to encourage all district directors to meet regularly with their branch directors to schedule workloads and manage the product sampling process.

HHS also stated that FDA will instruct laboratory directors to prepare monthly work-plan schedules that include the number of surveillance samples that can be accepted from other districts. Interdistrict coordination and deviations from the monthly schedules will be the district directors' responsibility. The districts will also receive instructions requiring them to develop an inventory size that will permit the laboratory directors to manage sample processing within the time frames established by FDA.

Implementing these actions should improve the management of product sample flow into the district laboratories and the laboratory directors' ability to control the sample inventory, provided the district directors assure that investigations branch directors understand that adherence to sample collection schedules is required unless the district directors approve a specific deviation.

In commenting on our recommendation that FDA establish a policy that prohibits "dumping," HHS stated that FDA has a policy that encourages district directors to manage sample collection in a manner that produces a constant flow of surveillance samples from the investigations branch to the laboratory branch. HHS recognized that unusual events may interrupt the orderly flow of samples and, in an attempt to meet the sample collection quotas in FDA's field work plan, collection efforts by investigators may result in unusually large inventories of unanalyzed samples. HHS stated that the FDA task force will consider the impact of such sample collection efforts and recommend appropriate practices.

We believe FDA policy should specifically prohibit investigators from placing large numbers of surveillance samples in the sample inventory without assurances from laboratory directors that the samples can be timely analyzed. We believe that timely sample analysis, including surveillance samples, should take precedence over meeting FDA field work-plan sample collection targets.

Changes in Sample Analysis Documentation Practices Could Reduce Laboratory Processing Time

In carrying out their analytical work, laboratory analysts prepare certain records to satisfy FDA's legal, scientific, and reporting needs. One of these records is the analyst work sheet, which provides a written account of analytical findings that either support regulatory action or classify samples as nonactionable. FDA's policy is that all sample analytical data must be recorded directly on the work sheet and its accompanying records and must be recorded when obtained.

For certain types of samples, FDA headquarters has authorized its field laboratories to abbreviate their sample test reports. However, the use of abbreviated reporting and the degree of abbreviation varies among laboratories. Requiring abbreviated reporting for nonviolative, surveillance samples would save FDA about 11.5 staff years of analyst time annually.

Current Reporting Requirements Are Designed to Support Legal Actions

FDA places great importance on the detailed recording and reporting of test results. A formal report of test results is required within FDA to support regulatory decisions. For violative products, FDA compliance officers must have the facts correctly, completely, and clearly on paper to make the proper regulatory decision. The accuracy and completeness of the analytical reports is important because analysts may be called upon to testify in court or answer questions months or years after the test was performed. At that time they must reconstruct, from the work sheet, details of the sample handling and testing. Also, when the work sheet is used in court testimony, it is subject to examination by opposing counsel.

For domestic samples the account of analytical findings is recorded on a standardized work sheet form, which has 14 designated sections and continuation sheets for the analyst to record the information requested or found. In addition, there are special adaptations of the standardized work sheet to facilitate the recording, reporting, and review of the results of certain types of laboratory examinations, such as industrial chemicals and salmonella testing. As discussed below, FDA permits the use of a different form for import samples.

FDA Allows Abbreviated Analyst Work Sheets in Some Instances

FDA has long recognized the importance of quick reaction on the release or detention of import shipments. Because of this concern, in April 1977, FDA implemented a streamlined import reporting system, which eliminated the recording of recurring data. This system permits the analyst to use an import sample summary form, instead of the standardized analyst work sheet, to report the test results. The summary form comes to

the analyst partially completed. The prerecorded data include information pertinent to 4 of the 14 designated sections on the standardized work sheet used for domestic samples. However, according to FDA, this system does not meet FDA's legal requirements for domestic regulatory samples because it does not provide an adequate chain of documentary evidence to support potential judicial actions. (Regulatory actions taken to keep imports from entering the country are administrative actions.)

In addition to the streamlined reporting for import samples, FDA allows individual laboratory directors to simplify analytical documentation for certain surveillance samples. Specifically, under FDA's Field Management Directive 77, district management has the authority to simplify documentation for some samples that are collected for information purposes only and will not be used in regulatory actions. Laboratory directors and supervisors we spoke with generally agreed that abbreviated reporting saves at least one-half hour of analyst's time for each sample.

The Use of Abbreviated Reporting Varies Among Laboratories

Although FDA headquarters has authorized its field laboratories to abbreviate their reports of tests on certain types of samples, it is not a requirement and guidance on abbreviated reporting is limited. For example, the Field Management Directive does not specify a form or standard format to be used by the laboratories in abbreviating their test reports. As a result, the form and extent of abbreviated reporting varied among laboratories. The degree of variation at the laboratories we visited ranged from using preprinted, fill-in-the-blank-type material on the standardized work sheet to doing little more than identifying the sample, citing the test methodology, and providing a brief statement of testing results. Details on our findings at two locations follow.

1. One laboratory director told us that his analysts used abbreviated reporting for about 75 percent of the samples they analyze. The laboratory uses two preprinted forms it developed for pesticide surveillance and drug surveillance samples. The director said that use of the abbreviated reports forms saves from one-half hour to 1 hour of analyst time.

2. Another laboratory director stated that abbreviated reporting is used for all pesticide work, representing about 30 percent of the laboratory's workload. The director estimated a minimum savings of one-half hour of analyst's time in preparing the abbreviated form the laboratory had developed.

We believe that there is potential for considerable time savings by adopting abbreviated reporting requirements for nonviolative surveillance samples. For example, of the 82,491 samples FDA tested in the 18-month period, over 37,000 were nonviolative surveillance samples. A half-hour reduction of analyst time on this number of samples equates to a savings of about $543,000 (based on FDA's $44 standard hourly rate for analysts),[1] or about 11.5 staff years of analyst time (based on FDA's standard of 1,075 hours of analyst testing time).

Los Angeles District Has Eliminated Most Documentation for Many Samples It Tests

FDA's Los Angeles district is responsible for monitoring pesticide residues in a large volume of produce. Recognizing that samples should be tested as quickly as possible to assure that the produce is available if FDA needs to take a regulatory action, the district has modified some of the traditional analytical procedures for pesticide surveillance samples to improve timeliness. One of the procedural modifications is the complete elimination of any type of analyst work sheet for most such samples, unless a violative product is identified.

The Los Angeles pesticide surveillance program, which involved over 4,000 samples in fiscal year 1984, covers both domestic and import samples.[2] Testing is done on an assembly-line basis by a team of analysts. If the products sampled are not violative, the test results for each sample are recorded on one line of a summary sheet. Only when violative products are detected is the standardized work sheet prepared.

The program involves more than just a reduction in paperwork, and the time saved by eliminating paperwork for most samples has not been precisely quantified. However, a 1983 FDA evaluation of pesticide sample test time compared the Los Angeles and San Francisco district laboratory operations. The San Francisco laboratory used the standard FDA analyst work sheet for recording information on all pesticide surveillance samples. The report concluded that the Los Angeles program had resulted in considerable time savings.

FDA headquarters is considering how the Los Angeles pesticide program could be implemented at other laboratories. In the interim, it has

[1]This rate is an estimate of the average salary, fringe benefits, and overhead costs applicable to FDA analysts FDA uses this rate to bill establishments for retesting products that have been reconditioned after an FDA regulatory action, such as a product seizure

[2]Los Angeles does not report data on these samples into the laboratory management system

informed field managers of the program and advised them that they can use whatever parts fit their situation.

Agreement on Reduced Documentation Is Lacking

While there is general consensus in the field on the need for reduced documentation in reporting nonviolative sample test results, one FDA headquarters official does not agree. The director of the Division of Field Science told us that most samples must be considered as potentially violative and this requires adherence to standard operating procedures. He stated that without a high volume of similar analyses, the use of abbreviated work sheets would be counterproductive.

In contrast, the laboratory directors and most laboratory supervisors we talked to agreed on the need for reduced documentation. For example, one director in a memorandum to the region stated:

". . We treat each sample as if it is going to the Supreme Court, and I think in the majority of cases this is a waste of time I have looked at what other Federal and State agencies do in report writing and none approach the extensive detail of FDA. If we would be willing to adopt abbreviated reports on the majority of our samples, we could probably save from 1 to 2 hours per sample Pesticide analysis could be significantly expedited if we set up pass fail criteria "

Conclusions

FDA laboratory documentation requirements add to the time needed to complete sample processing. To save time, FDA has allowed abbreviated reports of sample test results in some instances, but many field laboratories have not used the abbreviated report. We believe that there is potential for considerable time savings and more efficient use of resources by using abbreviated reporting for nonviolative surveillance samples.

Recommendations to the Secretary of HHS

We recommend that the Secretary direct the Commissioner of FDA to

- assess the simplified analytical documentation practices used by various FDA laboratories, including eliminating detailed step-by-step descriptions of the analyses performed on nonviolative samples, and determine their applicability to all FDA laboratories;
- define the universe of samples that should be covered by abbreviated reporting; and
- develop a standardized abbreviated form(s) and implement their use as FDA policy on a laboratory-wide basis.

Agency Comments and Our Evaluation

In its August 8, 1986, letter, HHS stated that the FDA task force will be asked to address our recommendations and propose appropriate agency action. (See app. VII.) HHS said that, while some laboratories have adopted abbreviated work sheets, FDA has not made this mandatory because it wants to maintain flexibility for individual district and laboratory directors to manage their operations. Such flexibility is, according to HHS, the keystone to the success of FDA's regulatory activities.

HHS believes that eliminating reporting on some samples would be counterproductive to FDA's consumer protection mission. According to HHS, FDA uses both present and past performances of products and firms in developing future regulatory posture, compliance programs, surveillance activities, import procedures, etc. HHS stated that the small amount of savings accrued from eliminating the reporting requirement for some samples would probably not outweigh the benefits of maintaining it.

We believe that HHS's position is contrary to FDA's practices. Our report discusses a sample processing reporting procedure used by FDA's Los Angeles district office that virtually eliminates any type of analyst work sheet for most pesticide surveillance samples, unless a violative product is identified. Instead, the Los Angeles analysts record the test results on one line of a summary document (see p. 36). We point out that FDA headquarters has informed its district directors of the Los Angeles pesticide program techniques and advised them to use any that fit their situation.

We believe that eliminating the standard analyst work sheet for nonviolative product samples would not affect FDA's ability to determine the performance of products and firms and develop appropriate future regulatory programs and activities. Most of the information used for these purposes would still be available on collection reports and summary sheets. Our recommendation has been clarified to reflect our intent that only the step-by-step description of the analyses performed on nonviolative samples be considered for elimination.

FDA Field Offices and Laboratories

Federal region	Location of		Laboratory capability
	Regional office	District office	
I	Boston, MA	Boston, MA	Yes
II	New York, NY[a]	Brooklyn, NY	No
		Buffalo, NY	Yes
		Newark, NJ	No
		New York Import, NY	Yes
		San Juan, PR	Yes
III	Philadelphia, PA	Baltimore, MD	Yes
		Philadelphia, PA	Yes
IV	Atlanta, GA[b]	Atlanta, GA	No
		Nashville, TN	No
		Orlando, FL	No
V	Chicago, IL	Chicago, IL	Yes
		Cincinnati, OH	Yes
		Detroit, MI	Yes
		Minneapolis, MN	Yes
VI	Dallas, TX	Dallas, TX	Yes
		New Orleans, LA	Yes
VII	Kansas City, MO	Kansas City, MO	Yes
VIII	Denver, CO	Denver, CO	Yes
IX	San Francisco, CA	San Francisco, CA	Yes
		Los Angeles, CA	Yes
X	Seattle, WA	Seattle, WA	Yes

[a]The New York Regional Laboratory Division provides laboratory support to the Brooklyn and Newark districts

[b]The Atlanta Regional Science Division provides laboratory support to the Atlanta, Nashville, and Orlando districts

Laboratory Time for Samples Processed by 19 FDA Field Laboratories—October 1, 1983, to March 31, 1985

Laboratory	Number of samples	Average	
		Calendar days	Workdays
Atlanta regional	9,002	19 1	14 1
Baltimore	4,698	20 6	15 1
Boston	4,503	26 5	19 4
Buffalo	2,900	20 2	15 0
Chicago	1,412	71 5	50 6
Cincinnati	2,987	53 7	38 2
Dallas	8,971	12 0	9 2
Denver	2,949	38 4	27 6
Detroit	1,779	87 6	61 6
Kansas City	2,948	27 2	19 8
Los Angeles	3,952	27 0	19 6
Minneapolis	3,903	44 0	31 4
New Orleans	4,058	45 3	32 5
New York Import	5,264	8 5	6 8
New York regional	4,498	78 8	55 6
Philadelphia	1,805	48 8	34 8
San Francisco	9,035	11 4	9 0
San Juan	1,321	29 2	21 2
Seattle	6,506	13 6	10 4
Nationwide	**82,491**	**28.4**	**20.7**

Laboratory Time for Samples Processed by 19 Field Laboratories in Fiscal Year 1984 and First 6 Months of Fiscal Year 1985

Table III.1: Laboratory Time for Fiscal Year 1984

Laboratory	Domestic compliance samples		Import compliance samples		Surveillance samples	
	Number of samples	Average calendar days	Number of samples	Average calendar days	Number of samples	Average calendar days
Atlanta regional	763	12 8	950	12 6	2,854	17 6
Baltimore	209	19 1	17	5 0	1,451	20 9
Boston	229	18 8	1,551	10 9	547	57 4
Buffalo	123	7 8	•	•	900	24 4
Chicago	133	15 1	219	27 3	189	122 1
Cincinnati	497	25 1	98	29 5	928	59 9
Dallas	422	13 3	1,465	3 7	2,297	18 1
Denver	160	31 3	36	14 2	948	28 5
Detroit	134	48 3	46	12 5	666	105 4
Kansas City	54	7 8	•	•	956	25 8
Los Angeles	268	16 7	1,309	15 6	904	52 9
Minneapolis	216	17 7	289	31 6	1,647	31 6
New Orleans	102	35 0	68	6 7	1,673	62 2
New York import	62	5 4	738	7 1	2,207	7 9
New York regional	384	37 9	56	14 1	796	164 9
Philadelphia	79	13 8	28	1 7	19	50 6
San Francisco	204	11 2	1,629	10 7	2,666	6 1
San Juan	39	25 1	•	•	170	19 8
Seattle	378	23 1	64	13 8	1,676	8 4
Nationwide[a]	**4,456**	**20.4**	**8,563**	**11.5**	**23,494**	**32.5**

[a]The combined total of the three sample categories excludes 12,830 samples that FDA did not classify as either compliance or surveillance

Table III.2: Laboratory Time for First 6 Months of Fiscal Year 1985

	Domestic compliance samples		Import compliance samples		Surveillance samples	
Laboratory	Number of samples	Average calendar days	Number of samples	Average calendar days	Number of samples	Average calendar days
Atlanta regional	1,171	15 3	210	10 9	2,072	23 7
Baltimore	515	23 0	356	9 6	754	22 8
Boston	378	28 0	1,301	11 4	294	118 5
Buffalo	203	18 3	5	6 2	1,063	17 7
Chicago	264	43 0	172	26 3	162	263 0
Cincinnati	558	27 9	96	38 8	369	147 3
Dallas	1,032	19 8	1,460	3 2	1,370	9 6
Denver	552	31 8	19	14 7	470	65 2
Detroit	268	133 8	37	19 1	363	73 0
Kansas City	259	27 1	9	4 7	988	37 8
Los Angeles	129	29 0	777	13 3	295	46 5
Minneapolis	298	23 3	175	10 6	761	76 5
New Orleans	166	62 2	312	4 7	1,073	44 3
New York Import	60	8 7	338	11 5	1,776	9 4
New York regional	1,132	26 7	34	52 1	713	115 6
Philadelphia	465	43 5	96	5 8	367	121 6
San Francisco	391	31 2	1,663	13 8	2,111	8 9
San Juan	142	23 4	150	11 4	309	46 8
Seattle	518	16 2	644	12 1	1,483	15 6
Nationwide	**8,501**	**29.1**	**7,854**	**11.1**	**16,793**	**38.3**

Import Sample Processing Time Frames

Types of analysis	Investigations branch[a]	Laboratory branch[a]	Compliance branch	Total workdays
Heavy metals/food standards	1	3	1	**5**
Sanitation/pesticides/ aflatoxin	1	5	1	**7**
Other non-microbiological	1	6	1	**8**
Microbiological	1	10	1	**12[b]**

[a]The investigations branch is allocated up to 2 days from collection of the sample to delivery to the laboratory branch However, if the investigations branch uses 2 days, the laboratory branch time is reduced by 1 day

[b]This is an average The range would be from 4 to 20 days depending on the analysis performed

Laboratory Time for Import Samples Processed by 19 FDA Field Laboratories—October 1, 1983, to March 31, 1985

Laboratory	Samples	Average workdays
Atlanta regional	2,164	8 7
Baltimore	1,674	7 4
Boston	2,897	8 7
Buffalo	1,037	4 1
Chicago	402	19 8
Cincinnati	345	25 6
Dallas	4,692	3 2
Denver	81	9 9
Detroit	241	24 5
Kansas City	57	4 9
Los Angeles	2,297	10 7
Minneapolis	538	16 9
New Orleans	849	8 0
New York Import	4,845	6 5
New York regional	200	13 1
Philadelphia	448	6 0
San Francisco	4,115	8 8
San Juan	495	8.0
Seattle	2,948	9 3
Nationwide	**30,325**	**8.1**

Inventory Time for Samples Processed by 19 FDA Field Laboratories in Fiscal Year 1984 and First 6 Months of Fiscal Year 1985

Table VI.1: Inventory Time for Fiscal Year 1984

	Total samples			Compliance samples			Surveillance samples		
		Average			Average			Average	
Laboratory	Number of samples	Calendar days	Work-days	Number of samples	Calendar days	Work-days	Number of samples	Calendar days	Work-days
Atlanta regional	5,549	7 0	5 7	1,713	4 7	4 1	2,854	6 7	5 6
Baltimore	3,073	6.0	5 0	226	7 3	6 0	1,451	5 1	4 3
Boston	2,530	12 6	9 6	1,780	5 5	4 8	547	34 0	24 4
Buffalo	1,629	12 9	9 6	123	2 5	2 5	900	14 8	10 9
Chicago	814	24 0	17 7	352	6 7	5 6	189	69 6	49 5
Cincinnati	1,964	20 6	15 1	595	6 9	5 7	928	34 6	24 7
Dallas	5,109	5 1	4 2	1,887	2 8	2 5	2,297	6 0	4 8
Denver	1,908	12 3	9 4	196	9 1	7 1	948	6 9	5 6
Detroit	1,111	43 9	31 2	180	19 8	14 5	666	58 6	41 3
Kansas City	1,692	8 6	6 7	54	2 3	2 3	956	11 1	8 4
Los Angeles	2,751	7 6	6 2	1,577	6 8	5 7	904	8 8	7 0
Minneapolis	2,669	21 6	15 9	505	16 0	12 1	1,647	18 5	13 7
New Orleans	2,507	25 7	18 7	170	13 7	10 2	1,673	29 7	21 6
New York Import	3,090	2 5	2 5	800	1 6	1 6	2,207	2 8	2 8
New York regional	2,619	54 6	38 7	440	13 3	10 1	796	111 1	77 6
Philadelphia	877	11 0	8 4	107	5 9	4 9	19	7 5	5 9
San Francisco	4,870	3 6	3 2	1,833	5 1	4 6	2,666	1 5	1 5
San Juan	720	4 1	3 5	39	1 7	1 7	170	1 9	1 9
Seattle	3,861	5 2	4 4	442	10 9	8 5	1,676	2 4	2 4
Nationwide	**49,343[a]**	**12.7**	**9.6**	**13,019**	**6.2**	**5.1**	**23,494**	**15.5**	**11.5**

[a]The combined compliance and surveillance sample totals do not match the number of total samples because FDA did not classify 12,830 samples as either compliance or surveillance in fiscal year 1984

Table VI.2: Inventory Time for First 6 Months of Fiscal Year 1985

	Total samples			Compliance samples			Surveillance samples		
		Average			Average			Average	
Laboratory	Number of samples	Calendar days	Work-days	Number of samples	Calendar days	Work-days	Number of samples	Calendar days	Work-days
Atlanta regional	3,453	5 4	4 7	1,381	3 6	3 4	2,072	6 7	5 6
Baltimore	1,625	5 8	4 9	871	5 4	4 6	754	6 2	5 1
Boston	1,973	18 4	13 8	1,679	7 3	6 1	294	81 8	57 9
Buffalo	1,271	9 3	7 3	208	8 6	6 9	1,063	9 5	7 4
Chicago	598	67 8	48 0	436	18 9	14 1	162	199 4	139 2
Cincinnati	1,023	42 8	30 6	654	6 8	5 7	369	106 6	74 8
Dallas	3,862	4 2	3 6	2,492	4 4	3.8	1,370	4 0	3 3
Denver	1,041	14 4	11 0	571	7 3	6.1	470	23 0	17 0
Detroit	668	56 6	40 2	305	83 9	59 0	363	33 6	24 4
Kansas City	1,256	18 9	13 9	268	17 8	13 1	988	19 2	14 1
Los Angeles	1,201	8 5	6 8	906	5 8	5 0	295	16 7	12 4
Minneapolis	1,234	37 1	26 7	473	11 1	8.7	761	53 2	37 8
New Orleans	1,551	27 0	19 9	478	21 3	15 6	1,073	29 5	21 8
New York Import	2,174	4 0	3 7	398	2 3	2 2	1,776	4 3	4 0
New York regional	1,879	34 3	24 8	1,166	8 7	7.1	713	76 0	53 7
Philadelphia	928	14 2	10 7	561	9 1	7 2	367	22 0	16 1
San Francisco	4,165	4 9	4 2	2,054	8 1	6 7	2,111	1 8	1 8
San Juan	601	12 3	9 5	292	2 8	2.8	309	21 3	15 7
Seattle	2,645	5 5	4 8	1,162	5 6	4 8	1,483	5 5	4 8
Nationwide	**33,148**	**14.5**	**10.9**	**16,355**	**8.7**	**7.0**	**16,793**	**20.1**	**14.8**

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington D C 20201

AUG 8 1986

Mr. Richard L. Fogel
Director, Human Resources
Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report, "Food and Drug Administration: Laboratory Analysis of Product Samples Needs to Be More Timely." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "FOOD AND DRUG ADMINISTRATION: LABORATORY ANALYSIS OF PRODUCT SAMPLES NEEDS TO BE MORE TIMELY" DATED JULY 1986

General Comments

We appreciate the opportunity to review the draft report which is quite comprehensive. It raises some significant issues and makes thought-provoking recommendations. FDA is appointing a task force whose charge will be to review the GAO report, to study field laboratory management, and propose appropriate policies and practices to enhance laboratory operations.

To this end, we find that the report would be more useful to FDA's task force if it incorporates the following suggestions:

1. A discussion of the complexities of the various methodologies by which samples may be analyzed and the impact on the time it takes for analysis would be helpful. This would set the data and recommendations in context and help to identify the reasons some laboratories' processes are slower than others.

2. A discussion of the milieu in which the laboratories were operating during the time-frame of the audit will allow the task force to determine the appropriateness of sample holding and processing times, given events that impacted on laboratory operations; and to assess the relevance of such events for future laboratory management.

3. In order to clearly delineate the line of responsibility for overall workflow management, the inclusion of interviews with district directors to reflect their role in scheduling and coordinating surveillance sample collections would be helpful.

4. Inclusion as an Appendix of GAO data analyses by class of product (e.g., foods, drugs, cosmetics, etc.), and by type of laboratory analysis performed would aid the task force in determining whether problems occur across-the-board or in specific areas. Any guidelines that result from the study will have to be tailored to specific product classes and analytical methods to be meaningful. Since GAO did some analyses of these factors, it would be beneficial to include them in the report.

5. Inclusion of an analysis of the causes for the apparent anomalies of the four districts with unusually high processing time would also enhance the usefulness of the report.

In addition to the above suggestions, we believe the report is overly simplistic in implying that laboratory inventories can be controlled by reducing sample collections to eliminate backlogs. The presence or absence of a laboratory backlog should not be a driving force in determining whether or not to collect a sample. Rather, the collective wisdom of investigators and district management should establish the criteria for sample collection commensurate with good public health protection, even when laboratories become overloaded and some analyses may have to wait while higher priority work is done.

Finally, the report fails to acknowledge that the quality of FDA's laboratory work has never been in question, nor does this report raise quality as an issue. The analyses done by field laboratories continue to be of the very highest quality, as evidenced by their acceptability in the courts, in public hearings and by the scientific community.

GAO Recommendation

We recommend that the Secretary direct the Commissioner of FDA to

1. --Establish time-frame guidelines for field laboratories' processing of all samples consistent with the four sample procession priority designators used by the laboratories.

Department Comment

As indicated above, as a result of this audit FDA is establishing a task force composed of laboratory directors and other appropriate personnel to study the issues GAO raised and make recommendations concerning laboratory management. One aspect of the study will be to examine processing time-frames and priorities, and to recommend a workable priority system with appropriate time-frame guidelines. The task force will also develop implementation and monitoring instructions that will provide for laboratory accountability while also recognizing that the timeframes are guidelines only and that laboratory management is the responsibility of district directors.

GAO Recommendation

2. --Evaluate field laboratory performance in meeting the time-frame guidelines.

Department Comment

We agree. FDA will establish procedures whereby appropriate headquarters units will be responsible for monitoring and evaluating the performance of all field laboratories with regard to meeting the requirements of established time-frames. Performance plans for Office of Regulatory Affairs (ORA) employees will include monitoring of time-frames when appropriate.

GAO Recommendation

3. --Change the laboratory management system (LMS) sample priority classifications to those used by the laboratories in setting processing priorities to (1) enable laboratory managers to better schedule the testing of samples and (2) provide laboratory managers greater monitoring capability over laboratory performance.

Department Comment

The task force will include an assessment of the LMS in its study and make recommendations commensurate with other recommendations resulting from the study.

GAO Recommendation

We recommend that the Secretary direct the Commissioner of FDA to establish procedures which

4. --require district offices' investigations and laboratory branches to coordinate and schedule the collection of surveillance samples;

5. --require the investigations branch to collect surveillance samples in accordance with the collection schedule developed with the laboratory branch, unless an emergency situation should arise;

6. --require laboratory directors to continue to prepare schedules for receipt of surveillance samples tested for other districts, and require these districts to follow the prepared schedules, unless agreements on deviations from the schedules are reached with the laboratory.

Department Comment

We believe that the district directors should be responsible for coordinating the activities of the investigations and laboratory branches within their own districts and with other districts. As an integral part of good management, many of the district directors currently hold informal meetings with the branch directors to plan their work schedules together. These informal meetings include discussions about inspections scheduling, collection of surveillance samples, laboratory backlogs and other relevant matters that impact on completing sample analyses in an efficient manner.

We recognize that there are exceptions to this style of management among district directors and will take steps to encourage all district managers to meet regularly with their branch directors to schedule workload and manage the sampling process. Also, when a laboratory in one district is servicing the needs of other districts, any

inter-district communications are best handled between district directors. FDA will, however, instruct laboratory directors to prepare monthly workplan schedules that include the number of surveillance samples that can be accepted from other districts. Coordination of inter-district activities and granting exceptions to the schedules will continue to be the responsibility of the district directors.

We believe the above approaches will result in the appropriate flow of surveillance samples into the servicing laboratories.

GAO Recommendation

7. --Require laboratory directors to determine an approximate inventory size which will permit the processing of samples within the time-frame guidelines established by FDA.

Department Comment

FDA will provide instructions to the districts requiring them to develop a reasonable and practical inventory size based on the ORA workplan, projected district-initiated surveillance activities and past performance. The inventory size should permit the laboratory directors to manage sample processing within the established time-frame. Supervisors and laboratory directors will continue to be responsible for completing sample processing in a timely manner.

GAO Recommendation

8. --We also recommend that the Secretary direct the Commissioner to establish a policy which prohibits the "dumping" of product samples into a laboratory's inventory.

Department Comment

We agree. FDA's policy has been and continues to be to encourage district directors to manage sample collection in such a manner as to produce a constant flow of surveillance samples from the investigations branches to the laboratory branches. Unusual events, however, may interrupt the steady influx of samples that is required for ideal sample-processing management. When such events occur investigations branches work exceptionally diligently to recoup the shortfall of collected surveillance samples that had been targeted in the Field Workplan. This extra effort may result in unusually large inventories of unanalyzed samples for short periods of time, placing an added burden on the laboratory. FDA is aware that this happens in some districts. Therefore, as a part of the overall review of laboratory management, the task force will consider the impact of such sample collections and recommend appropriate practices.

5

GAO Recommendation

We recommend that the Secretary direct the Commissioner of FDA to

9. --Assess the simplified analytical documentation practices used by various FDA laboratories, including the elimination of reporting on certain samples, and determine their applicability to all FDA laboratories.

10. --Define the universe of samples that should be covered by abbreviated reporting

11. --Develop a standardized abbreviated form(s) and implement their use as FDA policy on a laboratory-wide basis.

Department Comment

The FDA task force will be asked to address these recommendations and propose appropriate Agency action. We believe, however, that elimination of reporting on samples would probably be counter-productive to FDA's consumer protection mission. The Agency uses both present and past performance of products, as well as firms, in developing future regulatory posture, compliance programs, surveillance activities, import procedures, etc. Loss of such valuable data would not be in the best interest of consumers or of the industry. The small amount of savings accrued as a result of eliminating the reporting requirement on certain samples probably would not outweigh the benefits of maintaining it.

Also, while a number of laboratories have successfully implemented the use of abbreviated worksheets for their specific needs and program responsibilities, FDA has not made this mandatory because flexibility for field management is the keystone to the success of FDA's regulatory activities. The task force will look at abbreviated worksheets to identify surveillance programs where they can be used on a field-wide basis without compromising the flexibility of individual district and laboratory directors to manage their operations.

GAO's Evaluation of HHS's General Comments

The following comments have been extracted verbatim from HHS's August 8, 1986, letter (see app. VII). Each section of HHS comments is followed by our evaluation. Our evaluation of HHS's comments pertaining to our recommendations is presented on pages 23, 31, and 38.

HHS Comments

A discussion of the complexities of the various methodologies by which samples may be analyzed and the impact on the time it takes for analysis would be helpful. This would set the data and recommendations in context and help to identify the reasons some laboratories' processes are slower than others.

GAO Evaluation

As indicated on page 13, we did not assess the quality of sample testing by individual analysts or the time they took to complete specific analyses. Such assessments would require identifying and analyzing a variety of variables that determine what testing methodologies are used and the length of time needed to test individual samples. These could include the type of product analyzed, the purpose for the analysis, the experience of the analyst, the priority given the sample, and the type of equipment available. We believe that the FDA task force members, by virtue of their expertise, will be in a better position to determine the extent that complex analytical methodologies and the time used to perform analyses contribute to total processing time.

HHS Comments

A discussion of the milieu in which the laboratories were operating during the time-frame of the audit will allow the task force to determin the appropriateness of sample holding and processing times, given events that impacted on laboratory operations; and to assess the relevance of such events for future laboratory management.

GAO Evaluation

We recognize that unusual events, such as product recalls and emergency situations, may greatly disturb the normal sample analysis process (see p. 18), causing delays in the routine flow of compliance an surveillance samples through the laboratories. However, as we discuss in our report, we believe that FDA needs to establish better procedures control the collection of surveillance samples during and after the time these unusual events occur (see ch. 3). In this regard, HHS agreed to require that FDA instruct its laboratory directors to prepare monthly work-plan schedules that include the number of surveillance samples that can be accepted from other districts. Interdistrict coordination an

deviations from the monthly schedules will be the district directors' responsibility.

HHS Comments

In order to clearly delineate the line of responsibility for overall workflow management, the inclusion of interviews with district directors to reflect their role in scheduling and coordinating surveillance sample collections would be helpful.

GAO Evaluation

Our discussions with district directors at the FDA facilities visited did not focus on the directors' roles in scheduling and coordinating surveillance sample collection. We recognize that the directors have ultimate responsibility for the activities that occur within their districts. We were informed by an FDA headquarters official, however, that the laboratory directors were responsible for day-to-day management of the sample inventory.

HHS Comments

Inclusion as an Appendix of GAO data analyses by class of product (e.g., foods, drugs, cosmetics, etc.), and by type of laboratory analysis performed would aid the task force in determining whether problems occur across-the-board or in specific areas. Any guidelines that result from the study will have to be tailored to specific product classes and analytical methods to be meaningful. Since GAO did some analyses of these factors, it would be beneficial to include them in the report.

GAO Evaluation

Our review work did include some analyses of FDA's field laboratories' performance in processing samples in specific product classes using either microbiological analysis or chemistry analysis methods. However, we did not include the analyses in our report because we could not verify that the analytical methods used at the individual laboratories were sufficiently similar to make comparisons among the laboratories meaningful. Our analyses originated from information provided by FDA's Director of Field Science, who told us that the methods used to analyze these samples would be similar regardless of where the analyses were done. We did not corroborate this information with field laboratory personnel and, therefore, did not use the data to support our findings. The results of our analyses generally showed large variances in sample processing times among the laboratories similar to those shown in appendixes II and III of this report. We have provided these analyses to

FDA officials for their use in reviewing field laboratories' operations in general, and our findings in particular.

HHS Comments

Inclusion of an analysis of the causes for the apparent anomalies of the four districts with unusually high processing time would also enhance the usefulness of the report.

GAO Evaluation

Only one of the four laboratories with the highest average sample processing times as shown in appendix II was visited during this review Therefore, we did not include in our report an analysis of the specific causes for the high sample processing times at these laboratories. At the laboratory visited, we did not identify specific causal factors for the high average processing times other than those discussed in our report (i.e., lack of time-frame guidelines for all samples collected, inadequate control of sample inventories, and the use of overly detailed analytical reporting procedures for nonviolative surveillance samples).

HHS Comments

In addition to the above suggestions, we believe the report is overly simplistic in implying that laboratory inventories can be controlled by reducing sample collections to eliminate backlogs. The presence or absence of a laboratory backlog should not be a driving force in determining whether or not to collect a sample. Rather, the collective wisdom of investigators and district management should establish the criteria for sample collection commensurate with good public health protection, even when laboratories became overloaded and some analyses may have to wait while higher priority work is done.

GAO Evaluation

We do not believe that our position on controlling sample inventories is simplistic. The existence of an inventory backlog without assurances from laboratory directors that the existing samples can be timely analyzed should in fact be a driving force in slowing or stopping the collection of additional surveillance samples. We agree that the collection of compliance samples is beyond the control of the laboratory branch directors and the investigations branch directors. However, proper coordination and cooperation between these branches, both intra- and interdistrict, could help prevent large numbers of surveillance samples from sitting in the sample inventory for long periods. As indicated above, HHS

has agreed to require FDA to develop schedules for the collection of surveillance samples and placed the responsibility for approving changes to these schedules with the district directors.

HHS Comments

Finally, the report fails to acknowledge that the quality of FDA's laboratory work has never been in question, nor does this report raise quality as an issue. The analyses done by field laboratories continue to be of the very highest quality, as evidenced by their acceptability in the courts, in public hearings and by the scientific community.

GAO Evaluation

In response to the above statement, we have included on page 13 HHS's statement regarding the quality of the work performed by FDA's laboratories.

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