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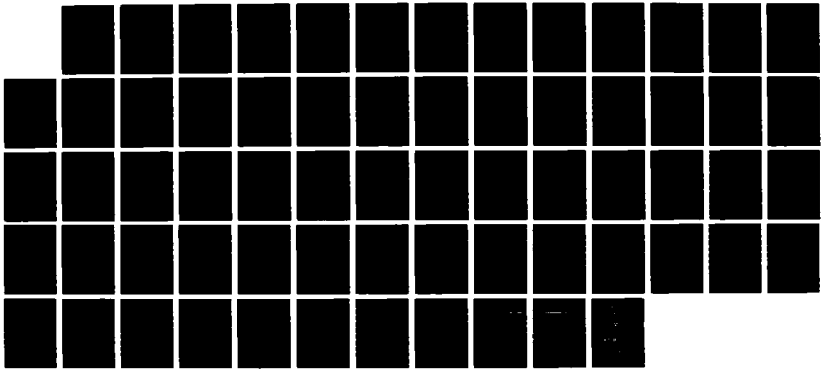

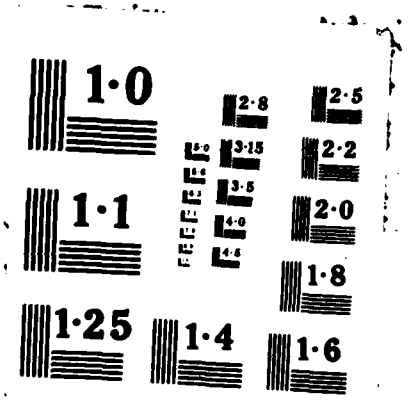
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United States General Accounting Office

GAO

Report to Congressional Requesters

December 1987

FOOD AND DRUG ADMINISTRATION

Insufficient Planning for Field Laboratory Consolidation Decisions

GAO/HRD-88-21

GAO

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

Human Resources Division

B-229234

December 4, 1987

The Honorable David Durenberger
United States Senate

The Honorable Thomas Luken
House of Representatives

The Honorable Jack Kemp
House of Representatives

The Honorable John LaFalce
House of Representatives

The Honorable Henry Nowak
House of Representatives

The Honorable Barbara Boxer
House of Representatives

In May 1986, the Food and Drug Administration (FDA) proposed to close or consolidate several of its field laboratories. At your request, we have reviewed the accuracy and completeness of FDA's closure/consolidation plans. This report discusses the adequacy of FDA's (1) criteria used to identify laboratories for closure or retention, (2) analysis of costs and savings related to the closings, and (3) assessment of the potential impact that closings will have on its ability to accomplish its mission.

We plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Secretary of Health and Human Services; the Commissioner of FDA; the Director, Office of Management and Budget; and other congressional committees and interested parties. We will also make copies available to others on request.

Richard L. Fogel
Assistant Comptroller General

Executive Summary

Purpose

The Food and Drug Administration's (FDA's) mission is to protect and promote the public health and the well-being of consumers. FDA's field laboratories play a critical role in accomplishing this mission by providing the scientific base that supports FDA regulatory activity. During any year, these laboratories test thousands of product samples for possible violations of FDA laws and regulations.

In May 1986, FDA proposed to close five of its field laboratory facilities which house five district laboratories, one specialty laboratory, and three research laboratories. This action would result in the relocation of about one-quarter of FDA's field analytical staff and the elimination of a laboratory presence in 5 of its 21 districts. This would increase to eight the number of districts that lack a laboratory presence.

At the request of Senator David Durenberger; Congressmen Jack Kemp, John LaFalce, Thomas Luken, and Henry Nowak; and Congresswoman Barbara Boxer, GAO reviewed the adequacy of FDA's (1) criteria used to identify laboratories for closure or retention, (2) analysis of costs and savings related to the closings, and (3) assessment of the potential impact the closings will have on its ability to accomplish its mission.

Background

FDA established its field laboratories in locations that were generally convenient to the locations of the food and drug manufacturing firms it regulates. In the past 6 to 8 years the number of FDA laboratory personnel has been reduced, while some of the laboratories have been expanded. As a result, about 35 percent of FDA's field laboratory capacity was not used in 1986. This unused capacity, combined with increases in operating costs (which were about $30 million in fiscal year 1986) and the need for major renovations to several facilities, prompted FDA to develop a plan to consolidate (close or merge) some of its laboratories.

FDA's plan recommended (1) closing the Buffalo, Cincinnati, Kansas City, Minneapolis, and San Francisco laboratories; (2) relocating the Boston laboratory to the nearby Winchester, Massachusetts, Engineering and Analytical Center laboratory; and (3) merging the collocated New York regional and New York import laboratories. FDA initially estimated that the proposed consolidations (the five closures and the mergers in Boston and in New York) would save over $3.7 million over the 6-year period ending in fiscal year 1992.

On July 16, 1986, the House Appropriations Committee directed that no laboratory closings occur in fiscal year 1987, and that FDA submit, with

its fiscal year 1988 budget request, a detailed estimate of costs versus savings for each of the five laboratories to be closed. The Senate Appropriations Committee also directed that no fiscal year 1987 funds be used for laboratory closings until it reviews GAO's report.

FDA merged the staffs of the New York City laboratories as of October 1, 1986. The Boston laboratory will be relocated when renovations are completed at the Winchester Center. In April 1987, FDA submitted a report to the Congress containing a revised costs/savings analysis for the five laboratories scheduled to be closed. The revised analysis showed a $165,000 net cost to the government compared to the May 1986 estimate of $3.7 million in savings. Elimination of the New York and Boston actions accounted for about $2 million of the change in the revised estimate.

Results in Brief

FDA's principal reason for proposing to close the five laboratories was to reduce the amount of excess capacity (about one-third of total capacity) in the field laboratory network. While steps should be taken to address the network's unused capacity, GAO believes that FDA did not use adequate criteria to reach its closure decisions. FDA's criteria were limited, for the most part, to the physical condition, and related aspects, of the facilities housing the laboratories. These criteria did not adequately address whether FDA could meet its current and future laboratory needs if the five laboratories were closed or whether cost-effective alternatives to closure were available to reduce its capacity.

FDA overstated some of the costs and savings in its original report and understated or omitted others. Although FDA addressed some of these matters in its April 1987 revised report, GAO believes that the revised analysis remains inaccurate and incomplete and that elements not adequately addressed could be significant.

FDA has not demonstrated that the field laboratory network remaining after the five laboratories are closed would be capable of meeting its analytical needs now and in the future. Likely increases in product sample transit and laboratory processing times would lessen FDA's regulatory effectiveness. Moreover, 61 percent of the excess laboratory capacity would remain after FDA's proposed actions are completed. GAO believes that before any laboratory closings, FDA should develop a long-range plan detailing present and future analytical needs and various alternatives on how these needs might be met, including costs/savings of the alternatives identified.

Principal Findings

Limited Decision-Making Criteria

FDA based its laboratory closure decisions primarily on the physical condition and the lease status of the facilities housing its laboratories, and did not adequately consider other factors, such as local workloads, potential replacement facilities, and local transportation modes. These factors were not considered because FDA believes that it can ship samples from across the nation to almost any location for analysis without reducing its regulatory effectiveness. (See p. 19.)

GAO believes that the criteria FDA used to reach its closure decisions were inadequate. While product samples can be shipped to almost any location, GAO believes there could be an increase in shipping costs, sample transportation times, and laboratory processing times. For example, GAO's analysis of fiscal year 1986 data shows a 3.5-day longer average transit time and over 10 days more laboratory processing time for samples with a high testing priority sent out of a district for analysis. GAO believes that FDA, in deciding which laboratories to close, should give more consideration to the number of and distance that priority samples would have to be shipped as a result of its consolidation decisions. (See pp. 22-25.)

Insufficient Consideration of Long-Range Program Needs

FDA made its closure decisions assuming that there would be no long-range increase in analytical staff and that its future workload would remain unchanged, even though it was aware of pending workload changes, particularly in the area of imported products.

FDA has acknowledged in congressional testimony that its consolidation plan may have been premature. (See p. 38.) Most recently, in an April 1987 report to the House Appropriations Committee, the FDA Commissioner recognized a greater need for laboratory personnel to deal with problems involving product tamperings, imports, and pesticides. The Commissioner also stated that final decisions on the five facility closings are subject to the results of GAO's review, Committee direction, and further consideration of FDA's emerging needs. (See p. 37.)

Recommendations

GAO recommends that before closing any FDA laboratories, the Secretary of Health and Human Services (HHS) direct the Commissioner of FDA to assess the present and future laboratory capacity to more closely reflect

FDA's analytical and regulatory needs. If a significant amount of unused laboratory capacity is identified, GAO recommends that the Commissioner be required to explore whether cost-effective alternatives to laboratory closure are available to reduce that capacity. (See p. 41.)

Agency Comments

HHS stated that it has reconsidered the laboratory consolidation initiative and decided not to pursue it. HHS stated that if the Department reconsiders consolidating FDA field laboratories in the future, an appropriate study will be undertaken. (See p. 63.)

Contents

Tables

Abbreviations

FDA	Food and Drug Administration
GAO	General Accounting Office
GSA	General Services Administration
HHS	Health and Human Services
ORA	Office of Regulatory Affairs

Chapter 1

Introduction

The Food and Drug Administration (FDA) is a public health agency whose primary goals are to protect and promote the public health and the well-being of consumers through the effective use and enforcement of all public health and consumer protection authorities available to the agency. FDA's activities are directed toward protecting the public health against impure and unsafe foods and cosmetics and ensuring that pharmaceutical, biological, and medical device products are safe and effective; that the use of radiological products does not result in unnecessary exposure to radiation; and that all FDA-regulated products are honestly promoted and labeled. FDA's basic authority for accomplishing its responsibility is derived from the Federal Food, Drug, and Cosmetic 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]

FDA's field laboratories play a critical role in protecting the American consumer from unsafe, ineffective, and mislabeled products. They provide a scientific base to support FDA enforcement/regulatory activity. During any year, the laboratories test thousands of product samples for possible violations of federal laws. Their analytical findings either support regulatory action or identify samples as being within the regulatory tolerances established by law.

Faced with increasing workloads and shrinking resources, FDA recently evaluated many of its activities to determine the most effective and efficient way to manage its resources. This effort included a number of evaluations and studies of its field laboratory organization. On May 5, 1986, FDA issued its Field Laboratories Consolidation Report, which summarized the data from the previous evaluations and recommended that the FDA Commissioner consolidate the field laboratory network by closing several laboratories and transferring staff and functions to other facilities. The Commissioner endorsed the report recommendations on May 23, 1986, but postponed further action until additional studies could be completed.

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

Structure and Staffing of FDA Field Laboratories

FDA consists of a headquarters staff, 10 regional offices, and 21 district offices[2] located throughout the country and in Puerto Rico. Four headquarters centers,[3] in conjunction with the Office of Regulatory Affairs (ORA), establish the basic policies FDA uses in implementing its regulatory activities. As FDA's investigative arm, ORA exercises direct line authority over FDA field operations, provides a central point to which headquarters officials can turn for field support services, develops programs and plans for activities between FDA and state and local consumer protection agencies, and administers FDA's federal-state program policy. The Office of Regional Operations is responsible for coordinating the inspection, testing, and enforcement activities of FDA's field operations.

FDA's 21 district offices perform most 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. The laboratories test product samples to determine whether they are in compliance with the laws and regulations enforced by FDA. The laboratories were originally established in all district offices, beginning in the mid-1930's, to enable them to analyze food and drug samples collected within their geographic areas.

FDA currently operates 26 field laboratories (see app. I), whose fiscal year 1986 operating costs were about $30 million. These facilities include

- 16 district laboratories;
- 2 regional laboratories (which provide analytical support to the other 5 districts);
- 2 specialty laboratories (the Winchester Engineering and Analytical Center, in Winchester, Massachusetts, and the Minneapolis Center for Microbiological Investigations); and
- 6 research laboratories.

While these laboratories primarily support the local districts (or regions), some of their work supports other districts (or regions) or involves national programs. For example:

[2]When the consolidation report was issued in May 1986, FDA had 22 district offices. The number was reduced to 21 in October 1986, when FDA reorganized its New York City operations (see p. 55).

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

- Regulatory microbiological analysis is done in 11 laboratories. For example, all such work in the Chicago region (Chicago, Cincinnati, Detroit, and Minneapolis districts) is performed in the Cincinnati district laboratory.
- "Total Diet" program analysis (which involves samples collected nationally) is performed in the Kansas City district laboratory.

The research laboratories and the Minneapolis Center for Microbiological Investigations are located at seven of the district laboratory locations. The Winchester Engineering and Analytical Center is located about 10 miles from the Boston district office location. The research laboratories' work focuses on developing methodologies for analyzing product samples. The Minneapolis center conducts in-depth microbiological analysis of national survey samples and sterility analysis research. The Winchester center serves as a national resource on resolving problems in analytical methods used to support regulatory actions and the development of new methods for analyzing products. This network of regulatory, specialty, and research laboratories, staffed with about 724 people, provides a scientific testing capability in support of FDA's consumer protection mission.

FDA district directors and laboratory managers use a computer-based laboratory management system to track product samples from collection through analysis and final disposition by the laboratories. Among the data this system contains for each sample are the collection date and location, the date received at the analyzing laboratory, the dates analysis began and ended, and descriptive information about the sample.

FDA Commissioner's "A Plan for Action"

In August 1984, the Secretary of Health and Human Services (HHS) directed the FDA Commissioner to chart FDA priorities and directions to meet the scientific and regulatory challenges of the 21st century. In July 1985, as a result of this charge, FDA issued A Plan for Action, which identified several global priorities and directions necessary for future management of the agency.

One of the priority areas identified in the action plan relates to FDA's internal management. The plan discusses several initiatives for improving agency management, including more prudently managing scarce resources and developing a mechanism for cost-benefit analysis of geographic location and consolidation of activities for FDA's field facilities. In May 1987 FDA issued phase two of its action plan, which builds on the success achieved from phase one. In this updated action plan, FDA

included short-term steps to provide better coverage of import products. One such step is enhancing field laboratory capabilities to process samples of imported products. The report was not specific on how this enhancement would be accomplished.

FDA's Laboratory Consolidation Initiative

In responding to the initiatives outlined in A Plan for Action, FDA has evaluated many activities to determine the most efficient and effective ways to manage its resources. In recent years, FDA has had to deal with budget reductions, increasing workloads, limited resources, and rapid technology advancements in all areas regulated by the agency. This has forced FDA to seek improvements in its internal management and to identify areas where a reduction or consolidation of resources could be accomplished. One area that has been identified is the organization of FDA's field laboratories.

FDA's May 1986 report recommended that its field laboratories be consolidated because of an increasing excess of total laboratory capacity and provided FDA's basis for determining which laboratories to close or consolidate. FDA estimated in the report that $3.7 million could be saved over a 6-year period from laboratory consolidations.

FDA stated that its overriding goal is to maintain a network of laboratories that will meet all its analytical program needs. More specifically, FDA wants a field laboratory organization that would

- ensure all laboratories are current and at or near state of the art,
- resolve the long-term field laboratory needs for the agency, and
- be more streamlined and cost effective.

The report also stated that the network of laboratories should be in locations convenient to the industries FDA regulates.

Reasons for Recommending Consolidation

FDA's report stated that the principal reason for recommending laboratory consolidations was the amount of excess capacity that existed in its field laboratory network. The report showed that 35 percent of analyst workstations (279 of 808) were vacant at the time the report was issued, with vacancies at all but two laboratories. The report attributed the vacancies to major cuts in resources over the last 6 to 8 years, along with a continuing reduction in personnel. The report also stated that since 1983 FDA had undertaken a number of initiatives dealing with the

problem. These included halting expansion plans for four laboratories and reducing the size of a fifth.

FDA's report also cited other factors that contributed to the recommendation that the field laboratory organization be consolidated:

- Some of the laboratories are housed in facilities that require extensive repairs and improvements.
- The cost of new leases for existing or replacement laboratory facilities can be expected to increase significantly.
- Closing facilities that house laboratories and renting office space for the remaining district office activities could result in substantial cost savings.

FDA concluded that the above factors, in conjunction with reductions in dollars and personnel resources available to it and similar budget constraints for the foreseeable future, required that some action be taken.

Laboratories Identified for Closure/Consolidation

FDA's report recommended the merger of two New York City laboratories; the closure of five laboratory facilities in FDA's Buffalo, Cincinnati, Kansas City, Minneapolis, and San Francisco district offices; and the relocation of the Boston laboratory to the Winchester Engineering and Analytical Center site within FDA's Boston district. The research laboratories at the Cincinnati and Kansas City district offices and the specialty/research laboratory at the Minneapolis district office would also be eliminated by these closure actions. The report identified four other laboratories (Baltimore, Detroit, New Orleans, and the consolidated New York facility) for possible future consolidation in a second phase.

Costs/Savings Analysis of the Consolidation Plan

FDA's report included a costs/savings analysis for each of the six laboratory facilities to be closed and for the consolidation of the New York City laboratories. These analyses included estimates of (1) the savings that would accrue from no longer maintaining a laboratory facility; (2) the costs of replacement office space to accommodate the districts' investigative, compliance, and administrative staff; and (3) the costs of moving laboratory staffs to other locations. FDA projected these analyses over a 6-year period and estimated overall savings of about $3.7 million for that period.

Status of Consolidations/ Closures

Following the FDA Commissioner's May 23, 1986, endorsement of the report recommendations, FDA drafted an implementation plan which discusses how laboratory staff, equipment, and workloads would be shifted as the planned laboratory consolidations/closures are carried out. It shows that the analytical staff from the laboratories scheduled to be closed (about one-quarter of its field analytical staff) would be relocated to other laboratories. The sample analysis workload handled by these laboratories would, for the most part, be transferred to the same locations as the staff.

The plan states that FDA's first and basic premise is that each person affected by a closing will be offered a job at the gaining facility. The general policy to be followed is one of "directed reassignments." In such actions employees are entitled to relocation expenses and are guaranteed continuation of current grade and pay levels in the new location. Employees refusing such transfers are subject to separation from employment. When the implementation plan was presented to the FDA Commissioner, he declined to approve it.

The House Appropriations Committee directed on July 16, 1986, that no laboratory closings occur in fiscal year 1987 and that FDA submit, with its fiscal year 1988 budget request, a detailed estimate of costs versus savings for each of the five laboratories. The Senate Appropriations Committee also directed that no fiscal year 1987 funds be used for laboratory closings until it reviews GAO's report.

In a July 30, 1986, memorandum, the FDA Commissioner stated that while he continued to endorse the concept of consolidation, he could not give approval to the proposed implementation plan at that time because it was possible that

- the Congress would delay any action in fiscal year 1987 by denying funds for laboratory consolidation and
- GAO was evaluating the FDA consolidation report and probably would not have a final report until 1987.

For these reasons he concluded that laboratory closings would be premature. This decision applied only to the five closings that would eliminate an FDA district laboratory presence.

Subsequently, FDA implemented the consolidation of the New York City laboratories. FDA officially merged their staffs and functions as of October 1, 1986. The relocation of the Boston laboratory will be implemented

when the ongoing renovations at the Winchester Engineering and Analytical Center are completed.

In April 1987, FDA issued a requested Report for the House Appropriations Committee Regarding the Potential Costs and Savings of Consolidating FDA Field Laboratories, which supplemented the May 1986 report. The April report contained updated information and a revised costs/savings analysis covering the closing of the five laboratories. The revised analysis assumed the same schedule of closings as the May 1986 report and showed a $165,000 net cost to the government in place of the May 1986 estimate of $3.7 million in savings for the 6-year period. The New York and Boston actions, estimated at $2 million, were eliminated from the revised 6-year savings estimate (see p. 32). The updated report did not result in any changes to the May 1986 list of closure/consolidation candidate laboratories.

Objectives, Scope, and Methodology

On May 9, 1986, Senator David Durenberger of Minnesota requested us to initiate a comprehensive review of FDA's Field Laboratories Consolidation Report and its recommendations. The Senator expressed concern that FDA's consolidation decisions were made without complete and accurate information, particularly with respect to FDA facilities in Minneapolis. On June 18, 1986, Congressman Thomas Luken of Ohio requested that we include the FDA Cincinnati laboratory within the scope of our review work. In a joint letter dated July 23, 1986, Congressmen Henry Nowak, John LaFalce, and Jack Kemp of New York requested that we review FDA's decision to close the Buffalo facility. On August 15, 1986, Congresswoman Barbara Boxer of California requested that we review the decision to close the San Francisco facility.

The primary objective of our review was to assess the accuracy, completeness, and relevancy of the information FDA used as a basis for its decisions to close specific laboratories. In carrying out the review, we did not evaluate the merits of consolidating laboratories or upgrading laboratory facilities and, therefore, do not have specific conclusions and recommendations in this area. To meet our objective, we evaluated (1) FDA's key criteria for making closure decisions to determine whether they addressed all aspects necessary for sound decisions, were relevant to the laboratory closing issue, and were consistently applied across the entire field laboratory network; (2) the accuracy and completeness of FDA's costs/savings analysis presented in its May 1986 report and its April 1987 update; and (3) the impact that consolidation will have on the laboratories chosen to absorb the staff and workload displaced by

laboratory closings, including the potential for adverse changes in laboratory productivity and sample processing timeliness. We also determined whether FDA gave appropriate consideration to the impact that laboratory consolidation will have on its ability to meet the agency's long-term regulatory responsibilities (3 years and beyond).

We interviewed FDA headquarters officials in Rockville, Maryland, and obtained and analyzed supporting documentation provided by those officials to gain an understanding of the (1) methodology FDA used in developing its report and 1987 update, (2) reasons for including or excluding particular types of data in its studies, and (3) basis for its conclusions and recommendations. We also met with the FDA Commissioner in November 1986 and presented our concerns regarding the adequacy of FDA's criteria used to determine which laboratories to close, the accuracy and completeness of the associated costs/savings analyses, and the integration of the closing/consolidation plan with FDA's long-range field laboratory needs.

We interviewed General Services Administration (GSA) officials in Washington, D.C., to obtain information on GSA's leasehold agreements for FDA's field facilities and on costs that might be incurred as FDA terminates its use of leased facilities. We also obtained information from GSA regarding the FDA facility being built in Seattle.

We visited the FDA laboratories targeted for closure in Buffalo, Cincinnati, Kansas City, Minneapolis, and San Francisco to discuss the information included in the consolidation report with district office and laboratory managers and to review pertinent records and files regarding laboratory operations. We also interviewed laboratory employees at each of these locations to obtain their perspective on FDA's recommendations and reviewed documentation provided by them. We did not visit the New York City and Boston laboratories because of the minor impact FDA's actions had on its personnel and product samples to be analyzed. Laboratory staff and functions will remain intact at these locations.

We also visited five of the six FDA laboratories identified to receive displaced staff and workload. These laboratories are in Atlanta, Chicago, Denver, Detroit, and Philadelphia. At each location we reviewed pertinent documentation and interviewed district and laboratory managers regarding the laboratories' capability to efficiently absorb the planned influx of analysts and product samples. We did not visit the Seattle laboratory because the facility currently in use is not the one identified to

receive transferred analysts. At the time we performed our review, construction of the new Seattle facility had not been started.

We obtained and analyzed FDA laboratory management system data on 60,160 product samples that were tested nationwide during fiscal year 1986. For each sample, we determined the amount of transit time and the amount of laboratory time. Transit time is the total time it took to transport samples from the location where they were collected to the location of the analyzing laboratories. Laboratory time is the total time the sample spent in the inventory waiting to be tested and the time required by the laboratory to complete the testing and to report the results. We grouped the samples by type (food, drug, etc.), by source (domestic or import), and by priority (compliance or surveillance) and summarized each grouping by collecting district and analyzing laboratory. Our analyses consisted primarily of comparing average sample transit times and average sample laboratory times among all field laboratories. Our analysis of laboratory times gave particular attention to the data for samples collected by a laboratory's local district compared to samples collected by other districts.

For purposes of our analyses, we defined the Atlanta regional laboratory's local district to be all three districts in the region (Atlanta, Nashville, and Orlando) and the New York regional laboratory's local district to be the Newark and Brooklyn districts. In addition, we defined the Kansas City laboratory's local district to include the St. Louis station. For all other laboratories, we defined the local district to be that in which they are located.

We excluded data on 11,465 samples from the data base. We excluded data on 7,346 samples related to FDA's total diet work because it lacked collecting district information, and we excluded data on 2,687 samples associated with state-operated pesticide surveillance programs. The remaining 1,432 excluded samples were generally related to nonregulatory projects, such as quality assurance tests and confirmation of testing methodologies for new products suggested by drug firms.

Our review was made in accordance with generally accepted government auditing standards except that we did not validate the data in the laboratory management information system. However, during a prior

review of FDA's field laboratory operations, we made a limited assessment of the accuracy of the FDA system data for fiscal year 1984.[4] This assessment showed a relatively small error rate and gave us no reason to believe that using the computerized data would misstate sample transit or laboratory time. Our work was performed between May 1986 and April 1987.

[4]Food and Drug Administration: Laboratory Analysis of Product Samples Needs to Be More Timely (GAO/HRD-86-102, Sept. 30, 1986).

Limited Evaluation Criteria Used to Identify Laboratories to Close

FDA's goal for its field laboratory network is to have a comprehensive network that is up to date, capable of meeting current and future laboratory analysis needs, convenient to good transportation routes and the industries FDA regulates, and able to serve the needs of the public for the next 20 years. However, FDA's May 1986 recommendations to eliminate laboratory analysis capability in five FDA districts and consolidate laboratories in two districts were based on criteria that focused principally on advancing the achievement of the first objective: an up-to-date laboratory network. The criteria were limited, for the most part, to the age, condition, and lease expiration dates of the physical facilities housing the laboratories. FDA did not fully consider its current and future laboratory needs, local district workloads, the geographical alignment of its laboratories, and the effect that shipping compliance (priority)[1] samples elsewhere for analysis could have on the timeliness of FDA's regulatory actions.

FDA's May 1986 report stated that the principal reason for its laboratory closure recommendations was to reduce the amount of excess laboratory capacity (about one-third of total capacity) that existed in the field laboratory network. According to FDA, "The primary purpose of this report is to . . . determine which laboratories to close or consolidate." However, FDA's proposed actions will eliminate less than one-third of the excess laboratory capacity that originally prompted the need for a laboratory consolidation plan. Moreover, because of the limited evaluation criteria FDA used to make its recommendations, there is little assurance that the proposed actions will leave FDA with an analytical laboratory capability that can adequately serve its current and future regulatory responsibilities.

FDA's Evaluation Focused Mainly on Physical Facilities

In its May 1986 report, FDA stated that it had identified those factors it believed needed to be examined to make a decision about whether to close, consolidate, or keep open each laboratory. The report categorized the factors as affecting either space utilization efficiency or program management efficiency and briefly discussed how each factor would affect a decision about any particular laboratory. FDA stated that these factors, which generally covered logistics, space utilization, operational

[1]FDA classifies samples 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 or wharf inspection, are used to support a regulatory action, and have a high testing priority. The latter are samples that FDA tests to obtain safety and other trend data about selected products from a local or national perspective and have a lower testing priority.

needs, and program needs, were not given equal weight in the decision process and were not relevant in all cases.

Our analysis of the May 1986 report showed that FDA's criteria for selecting candidates for closure were focused principally on the physical condition and ownership status of the facilities housing the laboratories. Other factors, such as laboratory location and workload, were not primary considerations in FDA's analysis but were selectively used to further justify some of its closure/retention recommendations. Laboratory location and workload, for example, were not primary factors because FDA believes that samples from across the nation can be shipped to almost any laboratory for analysis without any impact on regulatory effectiveness. Therefore, FDA believes the presence of analytical personnel at a given physical site that is close to where the product sample is collected is no longer necessary. However, we noted that the geographic location of the Dallas district laboratory and the district's import workload, as discussed on page 21, were cited as primary reasons for retaining this laboratory.

FDA First Ranked All Laboratory Facilities to Identify Closure Candidates

FDA's first step in deciding which laboratories to close was to rank each facility housing a field laboratory according to four key factors related to the physical facilities in which laboratories were housed. These factors were (1) condition/suitability of facility, (2) age of facility, (3) recent renovations done, and (4) whether FDA or the government owned the buildings and, if not, the time remaining on the buildings' leases.

To develop quantitative ranking criteria, FDA identified several descriptive categories pertinent to each key factor and assigned scores to each category. Using these criteria, FDA evaluated each facility housing a laboratory. The descriptive categories and their associated scores are shown in table 2.1.

Table 2.1: Factors and Categories FDA Used to Evaluate Laboratories

Key factor/descriptive category	Assigned score
Condition/suitability	
New	0
Good condition	2
Acceptable	4
Needs some work	8
Needs extensive work/unsuitable space	10
Age of facility	
Under 5 years/recently renovated	0
5 to 10 years	4
10 to 20 years	8
Over 20 years	10
Recent renovations done	
Extensive	1
Some	3
Minor	5
Ownership (leased/owned)	
FDA owned	1
Government owned	2
Over 5 years on lease	3
3 to 5 years on lease	4
0 to 3 years on lease	5

According to FDA officials, assigning scores to each criterion for each laboratory was accomplished by a panel of FDA headquarters personnel representing facilities management and program operations functions. The facilities management personnel had visited each field facility to assess its physical condition. Using this information and input from the FDA field offices, the panel used its collective judgment to assign the most appropriate score to each criterion for each laboratory. The scores were totaled to establish each laboratory's relative ranking. Since its evaluation focused on the physical facilities housing laboratories, FDA did not separately score and rank the six research laboratories and the Minneapolis Center for Microbiological Investigations, which share facilities with district analytical laboratories.

Using the total scores resulting from its evaluation, FDA assigned each laboratory to one of three groups: (1) current candidates for consolidation/closure (phase I), (2) candidates for possible future consolidation/closure (phase II), and (3) laboratories to be retained. Laboratories in the three groups and their total scores are shown in table 2.2.

Table 2.2: Laboratory Rankings and Scores

Closure/consolidation					
Phase I		Phase II		Retention	
Site	Score	Site	Score	Site	Score
Boston	30	New York Import	19	Winchester	14
Dallas	30	New York Region	19[a]	Atlanta	10
Kansas City	30	Detroit	18	Chicago	6
Minneapolis	30	New Orleans	18	Philadelphia	5
Cincinnati	28	Baltimore	16	Seattle	5
San Francisco	23			Denver	3
Buffalo	20			San Juan	2
Los Angeles	20				

[a]The report recommended the immediate merger of the two New York laboratories (they were located in the same building, on the same floor, adjacent to each other).

Appendix II shows the individual scores assigned to each category for each laboratory.

FDA Further Evaluated Closure Candidates Using Secondary Criteria

After using the four key factors to rank the laboratory facilities into the three groups (closure phase I, closure phase II, and retention), FDA applied secondary criteria to some of the phase I laboratories. As a result, FDA moved the Dallas and Los Angeles laboratories to the retention group, justifying their retention on the basis of local workload.

The secondary criteria addressed local workload, potential replacement facilities, transportation linkages, and vacant workstations. However, FDA did not develop weights for these criteria and apply them to all field laboratory facilities as it did with the four key factors. These criteria were applied only to those facilities within the phase I group, and only on a selective basis. For example, vacant workstations were considered only at the Buffalo facility.

Even when FDA applied secondary criteria to more than one of the phase I facilities, it did so inconsistently. For example, when FDA decided to retain the Dallas laboratory location based on local workload, it cited the high volume of imports, particularly Mexican imports, as justification for retention. However, FDA did not apply this same criterion in a similar manner to the San Francisco laboratory despite a comparable workload of import samples collected locally. In fiscal year 1986 the San Francisco laboratory had a total workload of 4,569 samples, of which 2,882 (or 63 percent) were locally collected import samples. In Dallas,

the laboratory had a total workload of 5,848 samples, of which 2,371 (or 41 percent) were locally collected imports.

Moreover, regarding the significance of the Mexican imports workload at the Dallas district laboratory, we noted that the workload does not seem overly large—FDA's fiscal year 1987 annual work plan schedules less than one person-year of analytical work for all 374 Mexican import samples scheduled for collection by the Dallas district office. We also noted that some Dallas district Mexican border sample collection points are located as close (in air miles) to the new, state-of-the-art Denver laboratory as they are to the Dallas laboratory.

Another example of inconsistent application of secondary criteria involved the San Francisco and Cincinnati laboratories. FDA stated that the direct air service from San Francisco to Los Angeles, Seattle, and Denver would allow the San Francisco laboratory to be closed and still permit FDA to provide adequate coverage for imports. This may be true, but on the same page of the consolidation report, FDA justifies closing Cincinnati because it is not a "principal air terminus," thereby increasing the difficulty of shipping samples to any laboratory facility located in the Cincinnati area. If this is true, it would seem that if the laboratory was closed, the samples collected by Cincinnati district investigators could not be shipped without difficulty and might result in some degradation in local program effectiveness. Thus, not being a "principal air terminus" could just as easily have been a reason for retaining the Cincinnati laboratory.

Other Important Factors Given Little Consideration

FDA did not adequately consider other factors essential to developing a comprehensive laboratory network. As a result, implementation of the consolidation plan approved by FDA could result in a laboratory system that does not adequately serve FDA's regulatory responsibilities now or in the future. In developing the plan for laboratory restructuring or consolidation, FDA did not fully consider such important factors as the productivity/efficiency of existing laboratories, whether the laboratories are located where they will be most effective in serving FDA's mission requirements and still be cost-effective, and FDA's long-range laboratory requirements.

Increases in Sample Transit and Laboratory Processing Times Likely to Occur

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. In two recent reviews,[2] we showed that untimely laboratory processing resulted in violative products reaching the consumer. We believe that the likely transit processing time increases resulting from laboratory consolidation will exacerbate this timeliness problem.

FDA contends that it can carry out a large-scale program of shipping product samples without affecting the productivity and efficiency of its field laboratories. Our review of FDA fiscal year 1986 laboratory management system data shows that transit and laboratory times increased when product samples were sent to the laboratories outside the collecting districts for analysis. This means that samples spent more time in transit before they were available to the testing laboratories and more time in the laboratory processing pipeline (inventory, analysis, reporting, review time). Such delays could have a negative impact on FDA's regulatory effectiveness. These factors were not adequately considered when FDA made its closure decisions.

We compared the amount of time it takes to ship compliance (priority) samples to laboratories within a district and the time it takes to ship similar samples to laboratories outside a district by summarizing fiscal year 1986 data from FDA's laboratory management system. As shown in table 2.3, in fiscal year 1986 it took an average of 3.5 days longer to get such samples to laboratories outside collecting districts than it took to get similar samples to laboratories within collecting districts.

[2]Laboratory Analysis of Product Samples Needs to Be More Timely (GAO/HRD-86-102, Sept. 30, 1986) and Need to Enhance FDA's Ability to Protect the Public From Illegal Residues (GAO/RCED-87-7, Oct. 27, 1986).

Table 2.3: Transit Time Comparison Between Local and Other District Collected Compliance Samples

Analyzing laboratories	Fiscal year 1986 No. of samples	Average calendar days
Local (within collecting district)	28,875	3.8
Other (outside collecting district)	3,733	7.3
Total	**32,608**	

In addition, table 2.3 shows that FDA analyzed most compliance samples locally—only about 11 percent (3,733 of 32,608) were analyzed in other districts.

Our analysis shows a 3.5-day-longer average transit time for compliance samples sent out of a district for analysis. We believe any increase in transit time for samples shipped from districts losing their laboratories will be less than this if FDA uses commercial air carrier service to ship all such samples (as it assumed in the consolidation report). However, we believe transit time will be at least 1 day longer. As shown in table 2.4, it took the Orlando district[3] 1 day longer to ship its import compliance samples to the Atlanta regional laboratory for analysis than it took to get similar San Francisco district collected samples to the San Francisco laboratory.

Table 2.4: Transit Time Comparison Between Orlando and San Francisco District Collected Import Compliance Samples

Collecting district	Analyzing laboratory	Fiscal year 1986 No. of samples	Average calendar days
Orlando	Atlanta	975	2.3
San Francisco	San Francisco	2,716	1.1

Any increase in laboratory time is of concern to the regulated industry. During our visits to Buffalo and San Francisco, we identified dozens of letters of concern from brokers, importers, and port authorities about delays, increased costs, and associated disruption to the import food community. Each day's delay in analyzing samples can mean that the industry bears an extra day's cost in warehousing/storing imported goods, with a similar delay in delivery and payment for the product by the purchaser.

[3]The Orlando district was used in this analysis because it had the largest import compliance sample workload of the five FDA districts without laboratory capability and, according to FDA officials, used commercial air transportation to ship most of these samples to Atlanta.

The prospect of laboratory closure so concerned the San Francisco Port Commission that, in January 1987, it offered to lease space, at a nominal cost to FDA, for a replacement laboratory in a new import facility it was about to build. FDA officials told us that this offer was not workable because it would require a $2-3 million expenditure to convert the space into a laboratory; the "nominal" annual rental cost was in excess of $200,000; the facility was located adjacent to a fumigation area, which would create air pollution problems for a laboratory; and the offer did not include office space for the remainder of the San Francisco district office. The FDA officials told us they had informed the port commission of their concerns but, as of August 1987, no amended offer had been made to FDA.

More significant than transit time increases are potential laboratory time increases for samples sent to other districts for analysis. During our visits to facilities slated for closure, district managers expressed concerns about an expected decline in services when they have to rely totally on a distant laboratory. Table 2.5, which shows laboratory time differentials between home district and other district analysis of fiscal year 1986 compliance samples, indicates that they have a basis for concern.

Table 2.5: Laboratory Time Comparison Between Local and Other District Collected Compliance Samples

	Fiscal year 1986	
Analyzing laboratories	**No. of samples**	**Average calendar days**
Local	28,875	14.9
Other	3,733	25.6
Total	**32,608**	

These compliance samples averaged over 10 days more laboratory time when analyzed outside the local district.

In commenting on the potential time increases for samples shipped from districts losing laboratories, FDA officials told us that any increases would be offset by increased productivity resulting from economies of scale in the operations of the laboratories remaining after consolidations. However, they could not document this assertion. Several district and laboratory directors at the five laboratories recommended for closure stated that the separation of the collecting investigators and the laboratory staff analyzing the samples would result in a reduction of regulatory effectiveness.

According to an FDA May 1982 field management directive, FDA's policy is that, when practical, analytical capabilities should be part of a district's overall functions. The directive states that "Past experience has shown that on-site analytical capabilities have improved efficiency of compliance operations by the close working relationship between investigators/inspector-analysts and district's management capability of establishing priority in sample analysis."

Laboratory Location Should Have Received Greater Consideration

Part of FDA's goal for its field laboratory network is to have state-of-the-art laboratories that are located near the industries it regulates. However, if FDA were to carry out its laboratory closure plans, there would be a degradation in the laboratory alignment with its regulated industries because FDA did not fully consider such factors as the amount of local district office generated sample workloads and the types of analyses done at laboratories targeted for closure.

Examining fiscal year 1986 data from FDA's laboratory management system, we noted that some laboratories have large, locally generated sample workloads, while others have smaller local workloads and rely on other districts for much of their total workload. For example, in 1986 the San Francisco laboratory, which FDA would eliminate, analyzed about 8 percent of total samples tested, of which 98 percent were collected within FDA's San Francisco district. Furthermore, over 72 percent of this workload was compliance samples. In contrast, the Denver laboratory analyzed about 2 percent of the 1986 samples, of which 40 percent were collected outside the Denver district. FDA data indicate that the San Francisco district is also the fourth largest entry point for food imports, with over twice the number of imports[4] as the Dallas district, where FDA decided that a laboratory presence should be retained.

Also, by closing the Cincinnati laboratory, FDA's Region V, which includes the Chicago, Cincinnati, Detroit, and Minneapolis districts, will no longer have the capability to analyze microbiological samples. All such samples collected by the four districts would be shipped outside the region for analysis.

[4]Based on 3-year average, 1981-83.

Proposed Consolidations May Not Result in a Laboratory Network That Meets FDA's Future Needs

FDA did not forecast what its future laboratory needs would be. Consequently, how well the planned field laboratory configuration will be capable of meeting future needs is unknown. Not fully considering the future impact of its decisions could place FDA in a position where it is unable to adequately respond to new problems within its regulatory responsibilities.

The Commissioner's July 1985 A Plan for Action was cited as the primary guidance for moving the agency into the 21st century. This action plan did not specifically discuss future analytical needs and laboratory capabilities. However, the action plan stated that FDA will develop a long-range planning process to establish priorities and consolidate activities that are duplicative, and a facilities plan that includes an analysis of the geographic location and consolidation of activities within field facilities. Also, part of FDA's stated goal for its field laboratories is to develop a laboratory network that is "able to serve the needs of the public for the next 20 years."

Despite these apparent recognitions of the need to assess future requirements, we found no evidence that FDA considered its future analytical needs or laboratory capabilities in deciding which laboratories to close. An example of this is FDA's decision to implement its consolidation plan independent of an ongoing study of the role of field research.

ORA officials told us that FDA is reevaluating the need for its research center laboratories, including the Minneapolis Center for Microbiological Investigations. They further stated that the research laboratories would likely be phased out and their staff integrated into the regulatory analysis laboratories. FDA's consolidation plan would result in the relocation of two research laboratories and the Minneapolis center (staff, functions, and equipment). It seems to us that FDA should resolve the question on the role of field research before it relocates research activities. By so doing, FDA would be better able to determine its research needs and the best locations for laboratories to meet these needs.

Implementation of the consolidation plan will still leave FDA with at least two laboratories in its network that are not up-to-date. Both the Dallas and Los Angeles laboratories' ranking scores made them closure candidates, but as discussed on page 21, FDA decided it needed laboratories in both locations.

While FDA is seeking replacement facilities in both cities, previous renovation and replacement initiatives were long and unsuccesful. For example, in a March 4, 1986, memorandum, the director of FDA's Dallas Region responded to a question regarding GSA's activities with respect to finding a new facility for FDA. In the response he explained that about 8 years earlier, FDA had prepared its initial space request for GSA, but GSA was unsuccessful in securing what FDA needed. FDA has obtained direct leasing authority for the replacement of its Dallas and Los Angeles facilities. However, as of April 1987, FDA had been unsuccessful in obtaining replacement space.

Consolidation Plan Will Not Fully Eliminate Vacant Workstations

FDA's May 1986 report stated that the principal reason for recommending laboratory consolidations was the amount of existing excess laboratory capacity. The report showed that 35 percent of analyst workstations (279 of 808) were vacant at that time, with vacancies at all but two laboratory locations.

FDA reduced its reported amount of excess laboratory capacity by one-third in its April 1987 report to the House Appropriations Committee. FDA also revised its count of total field laboratory workstations from 808 to 733. The report showed a reduction of 91 (from 279 to 188) vacant workstations. The reduction reflects (1) minor staffing changes (additions and attritions) at various laboratories, (2) the elimination of 16 workstations in the Boston and Winchester Engineering and Analytical Center laboratories, (3) the addition of 22 vacant workstations that will result from the Seattle building project, and (4) the elimination of over 80 vacant workstations in the New York regional laboratory as a result of a reevaluation of laboratory space usage.

FDA's May 1986 report did not accurately portray the cause of the problem. The report attributed the vacancy problem to major cuts in resources over the last 6 to 8 years, along with a continuing decline in personnel. The report also stated that since 1983 FDA has undertaken a number of initiatives to deal with the problem. These included halting expansion plans for four laboratories and reducing the size of a fifth. However, the report did not explain that during the last several years, FDA carried out several laboratory expansions that contributed to the vacancy problem by adding 65 workstations,[5] nor did it show that the ongoing new construction projects will add 30 more workstations in Philadelphia (8) and Seattle (22).

[5]Includes recent workstation expansions in Atlanta (42), Chicago (5), and Denver (18).

In FDA's April 1987 report to the House Appropriations Committee, it stated that "Several laboratories' analytical capacity will increase due to renovations . . ." and pointed out that these "were planned before the consolidation proposal . . ." FDA made no specific mention of the 22 additional workstations resulting from the Seattle construction project and did not report on the excess capacity it created as compared to that created by major cuts in resources and declining staff levels.

About 74 of the 188 vacant workstations (about 39 percent) will be eliminated by FDA's closure of the five laboratories. Commenting on the remaining 114 vacant workstations in the April 1987 report, FDA stated that they may be reduced by future consolidations (phase II) or will allow for growth in response to changing budgetary priorities (see ch. 4).

Although the FDA consolidation plan does not fully address the laboratory workstation vacancy problem, FDA's plan for relocations of staff and work from the five closed laboratories appears to be technically feasible. During our visits to the five FDA laboratories slated to receive the bulk of staff and workload transfers (exclusive of Seattle, where a new laboratory is to be built), our observations and interviews led us to conclude that the laboratories seemed capable of absorbing the planned infusion of analysts and product samples. However, we also noted that three laboratories (Baltimore, Detroit, and New Orleans) slated to receive staff and/or work from the five laboratories targeted for closure are themselves candidates for future consolidation. (App. I details the potential staff and workload transfers to the three laboratories.)

Alternatives to Laboratory Closure/ Consolidation Not Considered

In developing its consolidation recommendations, FDA did not formally consider options or explore alternatives to laboratory closure/consolidation. That is, FDA assumed that closing laboratories was the appropriate action to deal with the workstation vacancy problem. While we agree that good management practice requires that FDA take reasonable and cost-effective action to reduce the cost of leases for unused laboratory space, we believe that it should have considered alternatives to laboratory closings before deciding on such actions, with all their attendant impacts and ramifications. Options that FDA might have considered as alternatives to closings include (1) reducing laboratory space, (2) subleasing laboratory space to other agencies, and (3) establishing replacement laboratories with capacities tailored to their regulatory analytical work needs or other specialized analysis needs.

Laboratory Space Reduction

The cost of leases for unused laboratory space could be reduced by converting it from specialized space (with the highest square footage cost) to storage or office space (with lower square footage costs). For example, in the Buffalo district, which now pays $190,903 ($20.93 per square foot) for 9,121 square feet of laboratory space that has less than 50-percent utilization, FDA could convert one-half of the laboratory space to office and/or storage space costing $12.07 and $8.53 per square foot, respectively. Such a reclassification of space could save FDA from about $40,000 to $56,000 annually. In locations where FDA is in government-owned buildings (such as New York), FDA might consider returning the excess space to GSA.

Subleases

Another option that FDA might consider is subleasing some of its excess unused laboratory capacity to other government (state and federal) agencies with laboratory needs. We noted during our field visits that a state agency chemist currently uses space in one field laboratory.

Design Considerations

A third option that FDA might consider is to stop creating additional workstations. As FDA renovates/replaces its outdated laboratories, it should make an effort to correlate replacement laboratory workstation capacity with what is needed to handle the expected workload. For example, the May 1986 consolidation report states that FDA has long-range plans to consolidate its microbiological analysis work into four laboratories—Atlanta, Denver, New York, and Seattle. We noted, however, that FDA's plans for replacing its Los Angeles district laboratory include work space devoted to microbiological analysis. If FDA plans to phase this type of work out of the Los Angeles laboratory, replacement facilities should not include space for this type of work.

Another related option is the development of smaller, specialized laboratories to handle large volumes of locally generated priority work. For example, 75 percent (2,175 of 2,882) of the import samples tested by the San Francisco laboratory in fiscal year 1986 involved foodborne biological hazards (sanitation/filth) analyses. As an alternative to eliminating analytical capacity in San Francisco, FDA might consider developing a laboratory to test import sanitation samples.

Inaccurate and Incomplete Cost Analysis

Our evaluation of FDA's initial costs and savings estimates indicates that FDA's analysis did not accurately reflect the savings to be gained by closing the five laboratories. FDA's original analysis was inaccurate and incomplete in that some costs and savings were overstated and others were understated or omitted. FDA addressed some of these matters in its April 1987 revised report; however, the revised analysis remains inaccurate and incomplete. The costs and savings elements not adequately addressed could be significant. These elements should be fully considered before a decision is made to close any of the laboratories.

Initial Analysis

In the May 1986 consolidation report, FDA estimated that consolidation would save $3.7 million for the 6-year period ending in fiscal year 1992. This represented savings in rent for each district office facility[1] to be closed, less the costs to relocate analytical staff to other laboratories and the rent costs for office space for district personnel not relocated. Elsewhere in the report FDA recognized that there would be additional consolidation savings and costs. However, FDA specifically identified only one additional cost: an estimated $530,000 annual expense for shipping product samples from the collecting districts that would lose laboratories to other laboratories for analysis.

FDA's analysis assumed the closure actions would start in fiscal year 1987 and cover laboratories at seven locations: the five locations where FDA would eliminate district laboratory capacity plus the Boston and the New York locations where the laboratories were to be merged. The two mergers accounted for $2.0 million of the $3.7 million savings.

Revised Analysis

In November 1986 we informed FDA of our concerns about the accuracy and completeness of its cost analyses when we pointed out that the cost for moving analytical staff to other locations could be less than estimated and that the costs for shipping additional product samples, severance pay for employees who do not relocate, and moving laboratory equipment from closed laboratories should have been but were not included in its cost analyses. We also questioned the appropriateness of including the savings from laboratory mergers in New York and Boston in the overall savings estimate since these actions were approved and

[1] FDA's consolidation plan calls for the complete closure of the existing buildings housing the district offices and renting new office space for the investigations, compliance, and administrative management branches, which will remain active in the districts.

scheduled for implementation independently from the other recommendations in the May 1986 report.

In response, FDA revised its analysis. The revision was presented in the April 1987 report to the House Appropriations Committee. It deleted the savings estimate for the two mergers, increased the overall cost estimate for renting office space, and reduced the costs for moving analytical staff. It also included additional cost estimates for (1) the previously recognized but not included cost of shipping samples to other laboratories for processing, (2) the cost of severance pay for laboratory personnel who do not relocate, and (3) the cost of shipping the equipment from closed laboratories to other laboratories. The revised analysis again assumed closure actions would start in fiscal year 1987 and showed a $165,000 cost to the government in place of the previous estimate of $3.7 million in savings for the 6-year period ending in 1992. Despite these revisions, the updated analysis remains inaccurate and incomplete, as discussed below. The financial impact of the inaccuracies and omissions could be significant and should be addressed before making any laboratory closing decisions.

FDA Overstated, Understated, and Omitted Costs and Savings Elements

FDA's procedures for estimating the costs and savings associated with laboratory closures resulted in overstatements of analytical staff relocation costs and sample shipping costs and understatements of laboratory equipment moving costs. Also, FDA's analysis omitted other potentially significant costs and savings elements.

Analytical Staff Relocation Costs Are Overstated

FDA's revised analysis estimates overstate analytical staff relocation costs. FDA's estimates assume that 75 percent of analytical staff will relocate and that all who do so will take advantage of a house buy-out provision which, in combination with routine moving expenses, will result in an average relocation cost of $30,000 per employee.

FDA officials told us that the number of analytical staff who choose to move is likely to be less than the 75 percent used in the estimate. They said they used this estimate because they did not want to give the appearance of underestimating this cost.

During our visits to laboratories slated for closure, district managers, based on their knowledge of staff and staff intentions, said they believed that less than 75 percent would move. For example, at one of

the five laboratories we visited, 15 of the 39 laboratory professional staff would be eligible for early retirement at the time the laboratory was to be closed, and another 10 would be eligible if closure were delayed 2 years until December 31, 1989. Thus, a potential 64 percent of the professional staff at this one laboratory could retire rather than relocate.

In addition, FDA's $30,000 relocation cost estimate is likely overstated because it assumes that every employee who moves will need to use the house buy-out benefit. However, laboratory staff who relocate but do not own a house, who own a house but do not sell it, or who sell their house without FDA assistance would not use this buy-out benefit.

Sample Shipping Costs Are Overstated

FDA estimated that additional sample shipping costs that would result from the five closures would be $530,000 annually. It developed the estimate by assuming that all 11,761 samples analyzed in fiscal year 1985 by the five laboratories to be closed will be shipped to other laboratories using a relatively high cost, next-day-delivery rate. Both factors (number of samples and shipping rate) are overstated.

The number of samples shipped from the five districts scheduled to lose laboratories are likely to be less than the number they currently test because some samples are already shipped to the five locations from other districts and should be excluded from FDA's analysis. FDA workload information showed that about 2,200 such samples were included in the 11,761 total samples tested by the five laboratories in fiscal year 1985. These samples included the microbiological work currently performed by the Cincinnati laboratory for the Detroit, Minneapolis, and Chicago districts; the pesticide work performed by the Minneapolis laboratory for the Chicago district; and the pesticide work performed by the Buffalo laboratory for the Newark and Brooklyn districts.

Furthermore, it is unlikely that all of the additional shipped samples will incur the relatively high shipping cost FDA used in its estimate. Current FDA practice is to use other, less expensive forms of transportation, such as bus, to ship nonpriority samples, which made up about 58 percent of fiscal year 1985 workload for the five laboratories. Moreover, the director in one region, whose districts ship large volumes of priority samples, told us they use a less expensive air shipping service to deliver these samples.

In fiscal year 1985 FDA's total shipping costs for the entire field laboratory network were $297,700 for shipping about 35,000 samples. FDA's estimate for additional sample shipping costs resulting from closing the five laboratories was $530,000, or 178 percent of its total fiscal year 1985 shipping costs. In the May 1986 consolidation report, FDA described its estimate as a "worst case scenario" and recognized that it was unrealistic to believe that such high costs would be incurred. It had, in fact, developed another estimate in the May 1986 report that it stated was "probably much closer to what will actually occur . . ." Nevertheless, FDA again used the inflated estimate in its April 1987 response to the House Appropriations Committee request for a detailed estimate of costs versus savings for the five laboratories. FDA officials told us that it used the "worst case scenario" to develop its estimate because it did not want to give the appearance of understating the cost of closing the five laboratories.

Equipment Moving Costs Are Understated

FDA added the equipment moving cost estimate when it revised the cost analysis. The estimate was derived by assuming a $50 shipping charge for each piece of usable equipment, plus a $5,000 per site charge for special handling and packing for each of the five laboratories.

Although we did not determine the usable equipment inventories of the five laboratories, we noted that a mass spectrometer valued at about $260,000, one of the most costly pieces of a laboratory's equipment, was not included in the inventory list FDA used to develop its estimate. While this omission by itself would result in only a minimal understatement of equipment shipping expenses, it raises a question as to the accuracy and completeness of the equipment inventory FDA used to develop its estimate.

In addition, the shipping cost estimate does not include the costs to recalibrate equipment and repair any equipment damaged during the move. For example, three laboratory directors defined equipment moving to include dismantling, moving, reassembling, and recalibrating. One laboratory director estimated that moving his district's mass spectrometer would require dismantling and reassembling by the manufacturer at a minimum cost of $5,000. Two laboratory directors estimated that it could require at least 1 year's effort before a moved mass spectrometer was fully operational again.

Lease Termination Expenses Undetermined

FDA did not determine the lease termination expenses associated with laboratory closure. FDA's implementation plan acknowledges that FDA may have to pay rent for vacated laboratories that have been designated as agency unique space until that space is converted into rentable space by the lessor.

In addition, according to GSA officials, the original leases for two laboratories slated for closure had restoration clauses and restoration claims could result. Under the clause GSA or FDA must return the laboratory space to the same condition that it was in when FDA entered into the lease. GSA was unable to provide cost estimates for such restorations without a time-consuming cost survey.

Additional Personnel Costs and Savings Estimates Not Included

In addition to the facility costs discussed above, FDA did not provide estimates of either additional personnel savings or costs that could result from the proposed closures. Specifically, FDA plans will eliminate the need for some laboratory director positions and may eliminate the need for other positions by consolidating some supervisory units. As positions are eliminated, FDA can either reprogram them or eliminate them and reduce personnel costs. For example, early in the consolidation planning process, FDA identified a potential savings of three to five positions from closing laboratories (in a May 1985 study FDA estimated the annual cost of a position to be $30,000). Other personnel costs and savings that FDA did not recognize are listed in the following sections.

Pay Costs

- Unemployment compensation for those who do not relocate and have not found another job by time of laboratory closure.
- Lump sum accrued annual leave payable to those who quit or retire. Staff at one laboratory estimated this to exceed $80,000 for their location.

Staff Development Costs/Savings

- Additional training for new employees and lowered productivity by these employees for several years.
- Reduced training as staff are trained in specific job skills at fewer locations. Currently FDA trains staff or requires staff expertise to perform functions that use fractions of a staff year of time at various laboratories. To the extent that these functions can be combined, the demand for training would be reduced.

Equipment Savings Estimate Not Included

FDA's April 1987 cost analysis does not identify equipment savings. Although FDA officials assert that consolidation would result in a savings, FDA was unable to provide any estimates of the savings from changed or reduced equipment needs given the changed workloads and reduced number of laboratories.

Long-Range Program Needs and FDA's Consolidation Plan

FDA has not demonstrated that the field laboratory network remaining after its planned laboratory consolidations are implemented will be adequate to meet its analytical needs as it moves into the 21st century. Although FDA's stated goal is to maintain a field laboratory network that will meet the agency's long-term needs, emerging long-term needs and strategies for dealing with issues or problems were not fully considered in its decision-making process.

Consolidation Plan Not in Harmony With Other Initiatives

In making its closure decisions, FDA assumed that there would be no long-range increase in analytical staff and that its future workload would remain unchanged. FDA made these assumptions even though it was aware of pending workload changes, particularly in the areas of imported products and pesticide and microbial contamination of the food supply.

Several events after FDA's May 1986 consolidation report indicate that FDA did not give adequate consideration to increased or changing workloads for its field laboratories when making its closure decisions.

In his April 1987 report to the House Appropriations Committee, the Commissioner stated that since the development of the May 1986 consolidation report, FDA has been faced with an unprecedented number of product tamperings and with imported food and pesticide problems. He stated that due to these problems, FDA has a greater need for laboratory personnel than heretofore planned. In addition, the Commissioner stated that final decisions on laboratory closings are subject to the results of GAO's review, Committee direction, and FDA's further consideration of emerging needs.

In January 1987, just 8 months after FDA issued its consolidation report, the Commissioner approved a plan for reallocating FDA's field resources to meet a critical need for greater coverage of a wide variety of imported food problems. This reallocation will provide another 36 positions devoted to the coverage of imported food products.

In March 19, 1987, testimony before a subcommittee of the House Appropriations Committee, the Commissioner stated that FDA has been aware of the need to strengthen its surveillance of imported food for a number of years. He added that since 1971 the number of products under FDA surveillance has almost tripled and a larger proportion of these are ready-to-eat foods. Responding to this need, FDA increased staff-years devoted to imports by 24 percent since 1984. FDA's fiscal

year 1988 budget justification requests an additional 20 field positions devoted to the coverage of food safety activities. According to an FDA official, these new positions will be allocated to imported products, and 75 percent of them will be in the field laboratories.

In April 1, 1987, testimony before a subcommittee of the Senate Appropriations Committee, the Commissioner acknowledged that, in view of the need to do more work on imports, FDA's decision to close some field laboratories may have been premature. The Commissioner stated that he believes microbial contamination of food imports is a more significant problem than pesticide contamination. He added that FDA's microbial analysis methods are outdated, suggesting the need for newer methods, which take only days to complete, in place of current methods, which take weeks.

Earlier, during a February 1987 meeting, ORA officials told us that FDA was reevaluating its field microbiological analysis needs. This came up when we pointed out that the consolidation report indicated that FDA planned to centralize all microbiological work at four laboratories: Atlanta, Denver, New York, and Seattle. However, the specifications package for the replacement of the Los Angeles laboratory showed a microbiological analysis suite.

Although FDA apparently was aware of a significant problem in field resource allocations devoted to imported products and a need to adjust laboratory analysis capabilities, it made its laboratory closure decisions using the assumptions that there would be no increase in analytical staff and that the overall workload after consolidation would be the same. This is consistent with FDA's primary focus on present conditions of its physical facilities as the basis for justifying laboratory consolidations.

FDA's laboratory consolidation criteria resulted in recommending closing two laboratories involved in analyzing imported products (Buffalo and San Francisco) and one laboratory specializing in microbiological analysis of products (Center for Microbiological Investigations). Further, FDA's consolidation plan would close three research units, including one dedicated to microbiology (the Center for Microbiological Investigations' sterility research unit). FDA has not decided whether the Center for Microbiological Investigations and research unit missions will continue at the new locations.

The above information demonstrates the importance of estimating future program needs and establishing long-range plans based on those

needs. Had FDA fully implemented its laboratory consolidation plans, the loss of the import laboratories and the specialized microbiology laboratory might have significantly reduced its ability to timely respond to the increased volume of imported foods and adequately address problems developing in microbial contamination of the food supply. Conversely, a well-developed long-range plan detailing estimated future analytical needs and how they might be met could have served as a valuable tool in supporting the final laboratory closure decisions.

Conclusions, Recommendations, and Agency Comments

Conclusions

FDA's laboratory consolidation initiative was predicated on the existence of underutilized facilities (about one-third of laboratory analyst workstations were identified as vacant) and the need to eliminate this unused capacity, with its attendant costs. FDA's proposed solution to this problem, eliminating laboratory analysis capability from five districts and consolidating laboratories in two other districts, was based on a decision process that did not adequately consider FDA's current and future laboratory needs. Furthermore, likely increases in transit and laboratory times for product samples could lessen FDA's regulatory effectiveness. Moreover, 61 percent of the excess laboratory capacity would remain after FDA's proposed actions are completed.

While we concur with FDA that good management practice requires that it take reasonable and cost-effective action to deal with its unused capacity, that action should be taken only to the extent that unused capacity is in excess of current and future laboratory requirements. FDA has established specific objectives to guide the development and operation of its field laboratory network. We found, however, that its decision process for selecting laboratories to close and consolidate was focused primarily on the status of current laboratory facilities (physical condition and lease expiration dates) in an attempt to eliminate older, privately owned facilities from its laboratory network. Other factors—including laboratory location, the size and type of individual laboratory workloads, and the productivity and efficiency of field laboratories—should also be considered in determining which laboratories to close and which to keep open.

FDA needs to develop a field laboratory network plan that would provide the most efficient and cost-effective use of available resources now and in the future. FDA should develop the plan using its best estimates of current and future laboratory analysis needs and should consider all reasonable alternatives to laboratory closures. Alternatives that FDA might consider include reducing laboratory space or subleasing it to other agencies. In the absence of such a plan, eliminating laboratories from the network could place FDA in a position where it could not effectively address actual or potential problems with products that could be harmful to the public health, such as excessive pesticides in foods, imported products that fail to meet U.S. standards, and product tampering incidents.

Finally, the analysis FDA included in its May 1986 report and its April 1987 update incorporates inaccurate and incomplete cost and savings estimates. These inaccuracies and omissions could have a significant

impact on laboratory closure decisions. FDA should more fully consider and quantify all cost and savings elements to assure that the cost analyses it prepares relative to laboratory closings will give the Congress the best possible information for its consideration.

Recommendations to the Secretary of HHS

We recommend that the Secretary direct the Commissioner of FDA to defer decisions regarding laboratory closing/consolidation until FDA has developed a long-range plan based on its future program needs. This plan should identify the extent to which vacant workstations may be in excess of current and future laboratory needs. If a significant amount of unused and unneeded laboratory capacity is identified, we recommend that the Secretary direct the Commissioner to explore the full range of alternatives available to deal with the problem. In considering the closure/consolidation option, we recommend that the Secretary direct the Commissioner to

- identify laboratories for closure/consolidation by evaluating all appropriate factors, including forecasts of future analytical needs, to assure that the resulting laboratory network can support FDA's consumer protection mandate in a timely, cost-effective manner and
- develop accurate and comprehensive costs/savings analyses detailing the economic consequences of closure decisions.

Agency Comments

In an October 14, 1987, letter commenting on a draft of this report (see app. III), HHS stated that it has reconsidered the laboratory consolidation initiative and decided not to pursue it. HHS stated that if, at a future time, the Department has reasons to reconsider the feasibility of consolidating FDA field laboratories, an appropriate study will be undertaken.

FDA Field Laboratory Profiles

The following field laboratory profiles describe each geographically separate component of FDA's field laboratory network, including its status as of May 1986 and the personnel and/or workload each would gain or lose under FDA's proposed laboratory closure/consolidation plan. The number of "firms subject to inspection" is an FDA count of regulated establishments (manufacturers, warehouses, repackers, etc.) located in each FDA district. The available and excess "laboratory workstations" were taken from FDA's May 1986 field laboratory consolidation report. The proposed future "laboratory workstations" were taken from FDA's April 1987 supplement to its May 1986 report and subsequent information obtained from an FDA official. "Special laboratory role/capability" is GAO's identification of key analytical roles performed by the individual laboratories and is not intended to be all inclusive.

Atlanta Regional Laboratory

Area Served: Atlanta region—Atlanta district (Alabama, Georgia, North Carolina, and South Carolina); Nashville district (Kentucky, Mississippi, and Tennessee); Orlando district (Florida).	
Firms subject to inspection:	
Atlanta district	6,568
Nashville district	3,484
Orlando district	4,396
Total region	**14,448**
Recent relocations/expansions: Fiscal year 1986 expansion increased laboratory size from 14,505 to 27,619 square feet.	
Total regional staff:	
Atlanta district	68
Nashville district	48
Orlando district	58
Atlanta regional office	81
Total region	**255**
Laboratory staff:	
Analysts/technicians	49
Other	24
Total	**73**

(continued)

Laboratory workstations:	
Available	88
Excess	39
Proposed future	88
Laboratory workload (number of samples):	
Compliance:	
Domestic	2,483
Import	1,207
Total	**3,690**
Surveillance:	
Domestic	1,299
Import	594
Total	**1,893**
Overall:	
Domestic	3,782
Import	1,801
Total	**5,583**
Special laboratory role/capability:	
Microbiological analysis for Atlanta region (Atlanta, Nashville, and Orlando districts)	
Sterility analysis for Atlanta region	
Nutrition analysis for nation	
Functions to be received by laboratory:	
Cincinnati microbiological work	
Cincinnati research	
Minneapolis research	
Kansas City Total Diet work	
Kansas City chemical contaminant work	
Staff to be received by laboratory:	
Cincinnati microbiologists	
Cincinnati research center staff	
Minneapolis research center staff	
Kansas City Total Diet chemists	

Baltimore District Laboratory

Area served: Baltimore district (Maryland, Virginia, and West Virginia)	
Firms subject to inspection:	4,767
Recent relocations/expansions:	None
Total district staff:	107
Laboratory staff:	
Analysts/technicians	27
Other	11
Total	**38**

(continued)

Laboratory workstations:	
Available	36
Excess	9
Proposed future	36
Laboratory workload (number of samples):	
Compliance:	
Domestic	1,209
Import	255
Total	**1,464**
Surveillance:	
Domestic	579
Import	576
Total	**1,155**
Overall:	
Domestic	1,788
Import	831
Total	**2,619**
Special laboratory role/capability:	
Microbiological analysis for Philadelphia region (Baltimore and Philadelphia districts)	
Chemical contaminant analysis for Philadelphia region	
Drug bioequivalence analysis	
Functions to be received by laboratory:	
Cincinnati chemistry work	
Staff to be received by laboratory:	
Cincinnati chemists	

Boston District Laboratory

Area served: Boston district (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont)	
Firms subject to inspection:	5,950
Recent relocations/expansions:	None
Total district staff:	117
Laboratory staff:	
Analysts/technicians	20
Other	10
Total	**30**

(continued)

Laboratory workstations:	
Available	28
Excess	8
Proposed future	0
Laboratory workload (number of samples):	
Compliance:	
Domestic	320
Import	1,931
Total	**2,251**
Surveillance:	
Domestic	733
Import	3
Total	**736**
Overall:	
Domestic	1,053
Import	1,934
Total	**2,987**
Special laboratory role/capability:	
Microbiological analysis	
Laboratory functions/staff to be relocated:	
All to Winchester Engineering and Analytical Center	

Buffalo District Laboratory

Area served: Buffalo district (New York exclusive of New York City area—53 of 62 counties)	
Firms subject to inspection:	5,222
Recent relocations/expansions:	None
Total district staff:	83
Laboratory staff:	
Analysts/technicians	13
Other	7
Total	**20**
Laboratory workstations:	
Available	31
Excess	18
Proposed future	0
Laboratory workload (number of samples):	
Compliance:	
Domestic	650
Import	5
Total	**655**

(continued)

Surveillance:	
Domestic	771
Import	734
Total	**1,505**
Overall:	
Domestic	1,421
Import	739
Total	**2,160**
Special laboratory role/capability:	
Chemical contaminant analysis for Buffalo, Newark, and New York districts	
National pesticide expert on staff	
Laboratory functions to be transferred:	
Chemical contaminants in foods and feeds work to New York	
All other chemistry work to Philadelphia	
Laboratory staff to be transferred:	
All analysts to Philadelphia	

Chicago District Laboratory

Area served: Chicago district (Illinois)	
Firms subject to inspection:	6,383
Recent relocations/expansions: Relocation in fiscal year 1983 increased laboratory size from 8,577 to 16,100 square feet.	
Total district staff:	101
Laboratory staff:	
Analysts/technicians	19
Other	6
Total	**25**
Laboratory workstations	
Available	35
Excess	16
Proposed future	35
Laboratory workload (number of samples):	
Compliance:	
Domestic	566
Import	225
Total	**791**

(continued)

	Surveillance:	
	Domestic	219
	Import	8
	Total	**227**
	Overall:	
	Domestic	785
	Import	233
	Total	**1,018**
	Special laboratory role/capability:	
	Dioxin analysis for nation	
	Drug bioequivalence analysis	
	Functions to be received by laboratory:	
	Kansas City chemistry work except chemical contaminants, aflatoxins, and medicated feeds	
	Staff to be received by laboratory:	
	Kansas City chemists (except Total Diet chemists)	
Cincinnati District Laboratory and Research Center	Area served: Cincinnati district (Ohio)	
	Firms subject to inspection:	4,326
	Recent relocations/expansions:	None
	Total district staff:	91
	Laboratory staff:	
	Analysts/technicians	19
	Researchers	5
	Other	7
	Total	**31**
	Laboratory workstations:	
	Available	30
	Excess	11
	Proposed future	0
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	916
	Import	85
	Total	**1,001**
	Surveillance:	
	Domestic	585
	Import	48
	Total	**633**

(continued)

	Overall:	
	Domestic	1,501
	Import	133
	Total	**1,634**
	Special laboratory role/capability:	
	Microbiological analysis for Chicago region (Chicago, Cincinnati, Detroit, and Minneapolis districts)	
	Research center develops analytical methodology for measuring elements	
	Laboratory functions to be transferred:	
	Chemistry work to Baltimore	
	Microbiological work to Atlanta	
	Research to Atlanta	
	Laboratory staff to be transferred:	
	Chemists to Baltimore	
	Microbiologists and research center staff to Atlanta	
Dallas District Laboratory	Area served: Dallas district (New Mexico, Oklahoma, and Texas)	
	Firms subject to inspection:	8,286
	Recent relocations/expansions:	None
	Total district staff:	138
	Laboratory staff:	
	Analysts/technicians	30
	Other	9
	Total	**39**
	Laboratory workstations:	
	Available	31
	Excess	1
	Proposed future	31
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	2,547
	Import	1,403
	Total	**3,950**
	Surveillance:	
	Domestic	899
	Import	999
	Total	**1,898**
	Overall:	
	Domestic	3,446
	Import	2,402
	Total	**5,848**

(continued)

	Special laboratory role/capability:	
	Microbiological analysis for Dallas region (Dallas and New Orleans districts)	
	Pesticides in Mexican produce program analysis	
	Drug bioequivalence analysis	
	Function/staff changes:	None
Denver District Laboratory and Research Center	Area served: Denver district (Colorado, Montana, North and South Dakota, Utah, and Wyoming)	
	Firms subject to inspection:	4,953
	Recent relocations/expansions: All regional and district office staff scheduled to relocate in July 1987. Laboratory space increased from 5,800 to 15,825 square feet.	
	Total district staff:	97
	Laboratory staff:	
	Analysts/technicians	20
	Researchers	5
	Other	9
	Total	**34**
	Laboratory workstations:	
	Available	40
	Excess	20
	Proposed future	40
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	954
	Import	25
	Total	**979**
	Surveillance:	
	Domestic	328
	Import	7
	Total	**335**
	Overall:	
	Domestic	1,282
	Import	32
	Total	**1,314**

(continued)

	Special laboratory role/capability:	
	Illegal residues in meat and poultry analysis for nation	
	Medicated feed analysis for all districts except Kansas City, Minneapolis, and Chicago	
	Microbiological analysis for Denver and Kansas City regions	
	Research center develops analytical methodology for measuring drug residues in animal tissue	
	Functions to be received by laboratory:	
	Minneapolis microbiological and medicated feed work	
	Kansas City medicated feed work	
	San Francisco microbiological work	
	Laboratory functions to be transferred:	
	Domestic pesticide work to Seattle	
	Staff to be received by laboratory:	
	Minneapolis microbiologists	
Detroit District Laboratory and Research Center	Area served: Detroit district (Indiana and Michigan)	
	Firms subject to inspection:	6,064
	Recent relocations/expansions:	None
	Total district staff:	114
	Laboratory staff:	
	Analysts/technicians	18
	Researchers	5
	Other	7
	Total	**30**
	Laboratory workstations:	
	Available	37
	Excess	19
	Proposed future	37
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	597
	Import	44
	Total	**641**
	Surveillance:	
	Domestic	611
	Import	79
	Total	**690**
	Overall:	
	Domestic	1,208
	Import	123
	Total	**1,331**

(continued)

	Special laboratory role/capability:	
	Dioxin analysis for nation	
	Drug bioequivalence analysis	
	Research into methodology for measuring pesticide and industrial chemical residues	
	Functions to be received by laboratory:	
	Minneapolis chemistry work except aflatoxins and medicated feeds	
	Kansas City research	
	Staff to be received by laboratory:	
	Minneapolis chemists	
	Kansas City research center staff	
Kansas City District Laboratory and Research Center	Area served: Kansas City district (Iowa, Kansas, Missouri, and Nebraska)	
	Firms subject to inspection:	9,775
	Recent relocations/expansions:	None
	Total district staff (includes St. Louis Station):	133
	Laboratory staff:	
	Analysts/technicians	32
	Researchers	4
	Other	10
	Total	**46**
	Laboratory workstations:	
	Available	32
	Excess	0
	Proposed future	0
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	630
	Import	112
	Total	**742**
	Surveillance:	
	Domestic	717
	Import	9
	Total	**726**
	Overall:	
	Domestic	1,347
	Import	121
	Total	**1,468**

(continued)

	Special laboratory role/capability:	
	Total Diet program analysis	
	Research into analytical methodology in support of Total Diet analysis program	
	Laboratory functions to be transferred:	
	Medicated feed work to Denver	
	Total Diet work to Atlanta	
	Aflatoxin work to New Orleans	
	Chemical contaminant work to Atlanta	
	Chemistry work to Chicago	
	Research to Detroit	
	Laboratory staff to be transferred:	
	Chemists (except Total Diet staff) to Chicago	
	Total Diet chemists to Atlanta	
	Research center staff to Detroit	
Los Angeles District Laboratory	Area served: Los Angeles district (southern California and Arizona)	
	Firms subject to inspection	7,594
	Recent relocations/expansions	None
	Total district staff	168
	Laboratory staff	
	Analysts/technicians	41
	Other	10
	Total	**51**
	Laboratory workstations	
	Available	42
	Excess	1
	Proposed future	42
	Laboratory workload (number of samples)	
	Compliance	
	Domestic	456
	Import	2,751
	Total	**3,207**
	Surveillance	
	Domestic	2,263
	Import	2,559
	Total	**4,822**
	Overall	
	Domestic	2,719
	Import	5,310
	Total	**8,029**

(continued)

	Special laboratory role/capability:	
	Microbiological analysis	
	Pesticides in Mexican produce program analysis	
	Functions to be received by laboratory:	
	San Francisco import and drug work	
	Laboratory functions to be transferred:	
	Domestic pesticide work to Seattle	
	Laboratory staff changes:	None
Minneapolis District Laboratory and Center for Microbiological Investigations (Includes Sterility Research Center)	Area served: Minneapolis district (Minnesota and Wisconsin)	
	Firms subject to inspection:	5,845
	Recent relocations/expansions:	None
	Total district staff:	119
	Laboratory staff:	
	Analysts/technicians	35
	Researchers	4
	Other	12
	Total	**51**
	Laboratory workstations:	
	Available	40
	Excess	5
	Proposed future	0
	District	
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	940
	Import	252
	Total	**1,192**
	Surveillance:	
	Domestic	1,196
	Import	14
	Total	**1,210**
	Overall:	
	Domestic	2,136
	Import	266
	Total	**2,402**

(continued)

	Center for Microbiological Investigations	
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	257
	Import	32
	Total	**289**
	Surveillance:	
	Domestic	665
	Import	151
	Total	**816**
	Overall:	
	Domestic	922
	Import	183
	Total	**1,105**
	Special laboratory role/capability:	
	Chemical contaminant analysis for Chicago and Minneapolis districts	
	Sterility analysis for Chicago region	
	National microbiological analysis programs	
	Research into analytical methodology for sterility analysis	
	Laboratory functions to be transferred:	
	Medicated feed work to Denver	
	Aflatoxin work to New Orleans	
	Chemistry work, except aflatoxins and medicated feeds to Detroit	
	Microbiological work to Denver	
	Research to Atlanta	
	Laboratory staff to be transferred:	
	Chemists to Detroit	
	Microbiologists to Denver	
	Research center staff to Atlanta	
New Orleans District Laboratory and Research Center	Area served: New Orleans district (Louisiana and Arkansas)	
	Firms subject to inspection:	3,724
	Recent relocations/expansions:	None
	Total district staff:	79
	Laboratory staff:	
	Analysts/technicians	16
	Researchers	5
	Other	6
	Total	**27**

(continued)

Laboratory workstations:	
Available	21
Excess	5
Proposed future	21
Laboratory workload (number of samples):	
Compliance:	
Domestic	817
Import	455
Total	**1,272**
Surveillance:	
Domestic	1,197
Import	18
Total	**1,215**
Overall:	
Domestic	2,014
Import	473
Total	**2,487**
Special laboratory role/capability:	
National mycotoxin analysis	
Research into analytical methodology for measuring mycotoxins	
Functions to be received by laboratory:	
Minneapolis aflatoxin work	
Kansas City aflatoxin work	
Laboratory staff changes:	None

New York Regional Laboratory

Area served: New York district (nine counties in downstate New York) and Newark district (New Jersey)	
Firms subject to inspection:	
New York district	6,770
Newark district	5,987
Total	**12,757**
Recent relocations/expansions: None. However, the laboratory staff of the New York Import district were transferred into the laboratory in October 1986. The data that follow represent combined import district and regional laboratory information.	
Total regional staff:	
New York district	113
Newark district	88
Buffalo district (on-site laboratory)	83
San Juan district (on-site laboratory)	57
New York regional office	120
Total region	**461**

(continued)

Laboratory staff:	
Analysts/technicians	77
Other	26
Total	**103**
Laboratory workstations:	
Available	163
Excess	86
Proposed future	82
Laboratory workload (number of samples):	
Compliance:	
Domestic	2,682
Import	475
Total	**3,157**
Surveillance:	
Domestic	951
Import	4,218
Total	**5,169**
Overall:	
Domestic	3,633
Import	4,693
Total	**8,326**
Special laboratory role/capability:	
Sterility work for Boston, New York, Philadelphia regions	
Microbiology work for Buffalo, Newark, New York districts	
Functions to be received by laboratory:	
Buffalo chemical contaminants in foods and feeds work	
Laboratory staff changes:	None

Philadelphia District Laboratory

Area served: Philadelphia district (Delaware and Pennsylvania)	
Firms subject to inspection:	4,906
Recent relocations/expansions: Renovation is being carried out in fiscal year 1987 which will increase laboratory size from 8,400 to 8,710 square feet and add 8 analyst workstations.	
Total district staff:	107
Laboratory staff:	
Analysts/technicians	19
Other	5
Total	**24**

(continued)

	Laboratory workstations:	
	Available	34
	Excess	15
	Proposed future	34
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	768
	Import	269
	Total	**1,037**
	Surveillance:	
	Domestic	328
	Import	5
	Total	**333**
	Overall:	
	Domestic	1,096
	Import	274
	Total	**1,370**
	Special laboratory role/capability:	
	Drug bioequivalence analysis	
	Functions to be received by laboratory:	
	Buffalo chemistry work except for chemical contaminants (foods and feeds)	
	Staff to be received by laboratory:	
	All Buffalo analysts	
San Francisco District Laboratory	Area served: San Francisco district (northern California, Hawaii, and Nevada)	
	Firms subject to inspection:	7,249
	Recent relocations/expansions:	None
	Total district staff:	131
	Laboratory staff:	
	Analysts/technicians	29
	Other	9
	Total	**38**
	Laboratory workstations:	
	Available	29
	Excess	0
	Proposed future	0
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	590
	Import	2,723
	Total	**3,313**

(continued)

Surveillance:	
Domestic	1,090
Import	166
Total	**1,256**
Overall:	
Domestic	1,680
Import	2,889
Total	**4,569**
Special laboratory role/capability:	
Microbiological analysis	
Sterility analysis for Dallas, Denver, Kansas City, San Francisco, and Seattle regions	
Laboratory functions to be transferred:	
Microbiological work to Denver	
Import and drug work to Los Angeles	
Domestic chemical contaminant work to Seattle	
Laboratory staff to be transferred:	
All analysts to Seattle	

San Juan District Laboratory

Area served: San Juan district (Puerto Rico)	
Firms subject to inspection:	1,782
Recent relocations/expansions: Relocation in fiscal year 1986 increased laboratory size from 3,536 to 5,471 square feet.	
Total district staff:	57
Laboratory staff:	
Analysts/technicians	7
Other	4
Total	**11**
Laboratory workstations:	
Available	15
Excess	8
Proposed future	15
Laboratory workload (number of samples):	
Compliance:	
Domestic	212
Import	189
Total	**401**
Surveillance:	
Domestic	217
Import	202
Total	**419**

(continued)

	Overall:	
	Domestic	429
	Import	391
	Total	**820**
	Special laboratory role/capability:	
	Microbiological analysis	
	Function/staff changes:	None
Seattle District Laboratory and Research Center	Area served: Seattle district (Alaska, Idaho, Oregon, and Washington)	
	Firms subject to inspection:	5,095
	Recent relocations/expansions: None. However, future relocation is planned for fiscal year 1989 upon completion of a new building to house all Seattle region and district staff. This will increase analyst workstations by 22.	
	Total district staff:	97
	Laboratory staff:	
	Analysts/technicians	19
	Researchers	5
	Other	6
	Total	**30**
	Laboratory workstations:	
	Available	29
	Excess	10
	Proposed future	51
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	1,282
	Import	1,284
	Total	**2,566**
	Surveillance:	
	Domestic	1,213
	Import	24
	Total	**1,237**
	Overall:	
	Domestic	2,495
	Import	1,308
	Total	**3,803**

(continued)

	Special laboratory role/capability:	
	Microbiological analysis	
	Research into analytical methods for seafood analysis	
	Functions to be received by laboratory:	
	San Francisco, Los Angeles, and Denver domestic chemical contaminant work	
	Staff to be received by laboratory:	
	All San Francisco analysts	
Winchester Engineering and Analytical Center	Area served: All districts and regions	
	Firms subject to inspection: Not applicable	
	Recent relocations/expansions: Renovations are in process to accommodate Boston district laboratory staff.	
	Total staff:	75
	Laboratory staff:	
	Analysts/technicians	39
	Other	18
	Total	**57**
	Laboratory workstations:	
	Available	47
	Excess	8
	Proposed future	59
	Laboratory workload (number of samples):	
	Compliance:	
	Domestic	10
	Import	0
	Total	**10**
	Surveillance:	
	Domestic	841
	Import	436
	Total	**1,277**
	Overall:	
	Domestic	851
	Import	436
	Total	**1,287**
	Special laboratory role/capability:	
	Compliance testing of microwave ovens, television receivers, diagnostic X-ray equipment, sun lamps, mercury vapor lamps, and ultrasonic therapy devices.	
	Government-wide quality assurance, engineering product testing	
	Function/staff changes:	
	All Boston district laboratory work and staff will be relocated to Winchester.	

FDA's May 1986 Laboratory Scoring for Consolidation

Table II.1: Laboratory Scoring

	Key factors[a]																	
	Condition/suitability of facility					Age of facility				Recent renovation work			Ownership					
Location	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Score
Boston					10				10			5					5	30
WEAC		2							10	1			1					14
Buffalo			4						10	1							5	20
New York Region			4						10		3			2				19
New York Import			4						10		3			2				19
San Juan	0					0				1			1					2
Baltimore		2							10	1					3			16
Philadelphia		2				0				1				2				5
Atlanta		2				0						5			3			10
Chicago	0					0					3				3			6
Cincinnati					10				10		3						5	28
Detroit		2							10		3				3			18
Minneapolis/CMI					10				10			5					5	30
Dallas					10				10			5					5	30
New Orleans				8			4				3				3			18
Kansas City					10				10			5					5	30
Denver	0					0				1				2				3
Los Angeles			4						10	1							5	20
San Francisco					10				10	1				2				23
Seattle	0					0					3			2				5

[a]See table II.2 for rating category code definitions.

Table II.2: Rating Category Code Definitions and Points

Key factors/rating categories	Rating codes	Points
Condition/suitability of facility:		
New	1	0
Good condition	2	2
Acceptable	3	4
Needs some work	4	8
Needs extensive work/unsuitable space	5	10
Age of facility:		
Under 5 years/recently renovated	6	0
5 to 10 years	7	4
10 to 20 years	8	8
Over 20 years	9	10
Recent renovations work:		
Extensive	10	1
Some	11	3
Minor	12	5
Ownership (lease/owned):		
FDA owned	13	1
Government owned	14	2
Over 5 years on lease	15	3
3-5 years on lease	16	4
0-3 years on lease	17	5

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

OCT 14 1987

Mr. Richard L. Fogel
Assistant Comptroller General
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: Insufficient Planning For Field Laboratory Consolidation Decisions." The Department has reconsidered the laboratory consolidation initiative and decided not to pursue it. If, at a future time, the Department has reasons to reconsider the feasibility of consolidating the Food and Drug Administration field laboratories, an appropriate study will be undertaken.

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

Sincerely yours,

For Richard P. Kusserow
Inspector General

END

FILMED

MARCH, 1988

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