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GAO

Report to Congressional Requesters

September 1989

FDA RESOURCES

Comprehensive Assessment of Staffing, Facilities, and Equipment Needed

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Human Resources Division

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September 15, 1989

The Honorable Edward M. Kennedy, Chairman
The Honorable Orrin G. Hatch, Ranking Minority Member
Committee and Labor and Human Resources
United States Senate

The Honorable Quentin N. Burdick, Chairman
The Honorable Thad Cochran, Ranking Minority Member
Subcommittee on Agriculture, Rural
Development, and Related Agencies
Committee on Appropriations
United States Senate

This report responds to your October 20, 1988, request for an analysis of resource needs of the Food and Drug Administration (FDA). The report presents the results of a briefing given to your staff and contains recommendations to the Congress that will require FDA to make an agencywide assessment of its staffing, facilities, and equipment needs.

In accordance with your request and based on discussions with your staff, we obtained and analyzed available data and studies related to three areas: FDA staff requirements; staff recruitment and retention rates; and laboratory, space, and equipment needs.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the cognizant House committees and subcommittees, the Secretary of Health and Human Services, the Commissioner of FDA, the Director of the Office of Management and Budget, and other interested parties. We will make copies available to others on request.

Janet L. Shikles
Director, Health Financing
and Policy Issues

Executive Summary

Purpose

The Food and Drug Administration (FDA) is responsible for assuring the safety of the nation's foods, drugs, medical devices, radiological products, and cosmetics. Because of the wide range of products it regulates, FDA touches the day-to-day lives of virtually all citizens.

In a letter dated October 20, 1988, the Chairmen and Ranking Minority Members of the Senate Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies and the Senate Committee on Labor and Human Resources expressed concern over whether FDA has sufficient resources to meet its current and future responsibilities. In response to this request, GAO developed information on FDA's staffing requirements; staff recruitment and retention rates; and laboratory, space, and equipment needs.

Background

To carry out its responsibilities, FDA (1) performs premarket evaluations of drugs and medical devices, (2) conducts safety reviews of food and drug products, (3) provides criteria for use in manufacturing products, (4) conducts post-market surveillance of approved products, and (5) takes enforcement action against products that violate federal standards. Included in these responsibilities are investigations of product tampering incidents, such as cyanide in Tylenol and Chilean grapes, and expedited reviews of drugs that deal with public health crises, such as the acquired immunodeficiency syndrome (AIDS) epidemic.

In fiscal year 1989, FDA had about 7,200 staff and a funding level of over $512 million. FDA's resources are used to operate and support its headquarters staff, including 5 centers that regulate products; 6 regional offices; and 21 district offices. FDA also operates 19 field laboratories and 6 headquarters laboratories. (See pp. 8-9.)

Results in Brief

Due to staffing shortages, FDA officials have reported that there has been inadequate coverage of some activities. Since fiscal year 1980, new laws and other public health problems have significantly increased FDA's responsibilities while its staffing levels have decreased. FDA also reports experiencing difficulties in recruiting and retaining staff because of the disparity in pay and other benefits between the federal government and the private sector. Inadequate office and laboratory space and scientific equipment add to FDA's resource problems.

To fulfill its current responsibilities effectively, FDA estimates it needs about 2,000 additional staff. It also estimates that it needs about

$500 million to upgrade its headquarters facilities plus additional funding to upgrade its laboratory equipment. Although FDA appears to need additional resources, it has not determined its needs on the basis of a comprehensive agencywide assessment of all FDA activities. GAO believes, therefore, that before the Congress can adequately consider FDA's staffing and other resource requirements, the agency should develop a strategy to assure that resource requirements are accurately estimated. It should then identify and prioritize those activities and responsibilities that it believes it can undertake effectively given various budget and staffing levels.

Principal Findings

FDA Says It Needs 2,000 More Staff

Major legislation enacted during the 1980s cut across the range of FDA activities from premarket review of new drugs and medical devices to consumer education regarding food safety. This, coupled with the AIDS epidemic and product tampering incidents, placed added demands on FDA. Notwithstanding these increased demands, FDA currently has less resources than it had in 1980. (See pp. 11-12.)

FDA officials estimate that in order to make up for the agency's current staffing shortfall, more than 2,000 additional positions are needed to (1) replace those lost since 1980, (2) fully implement new legislative requirements, and (3) handle responsibilities related to AIDS and the regulation of medical devices. The President's fiscal year 1990 budget to the Congress calls for an FDA staffing level of 7,386, which would be about 1,800 less than FDA's estimated needs. The President's budget would also be more than 400 positions less than the agency had in fiscal year 1980. (See pp. 12 and 18.)

FDA's staffing estimate of 2,000 is based on a compilation of data from its various center and field office time and activity reporting systems. The various systems are not linked in a way that supports the preparation of a comprehensive assessment of current and future staffing needs. (See p. 18.)

Any comprehensive assessment should also consider the prioritization of an agency's activities. In this regard, in the mid-1980s, FDA convened a task force to study how to use its declining resources more efficiently and effectively. The task force proposed several approaches to improve

FDA's efficiency and effectiveness. FDA has considered and implemented many of the task force proposals. But it has not adopted others, and many of these continue to be relevant. For example, FDA has not (1) assessed, on an agencywide basis, all of FDA's activities and determined which ones could be accomplished in the face of limited resources; (2) considered shifting work, where appropriate, to industry and other federal agencies to assist FDA in accomplishing its mandates; and (3) made a study to identify activities no longer necessary. (See pp. 14-15.)

Staff Recruitment and Retention Problems

FDA also reported that it has experienced difficulty in filling senior-level positions. FDA data showed that during the last 6 years, the amount of time it took to fill 36 vacant Senior Executive Service positions ranged from at least 4 months to more than 5 years. Included were vacancies at the directorate, deputy directorate, and associate commissioner levels. FDA officials said that disparities in pay and fringe benefits, inadequate office and laboratory space, and the high cost of living in the Washington, D.C., area have hampered the agency's recruitment efforts. (See pp. 20-24.)

FDA has also had a difficult time in retaining scientists and engineers in nine critical specialties—particularly medical officers. From fiscal years 1985 through 1988, FDA lost from 18 to 22 percent of its medical officers each year. During this same period, the annual loss rate for three other specialties (biologists, biomedical engineers, and veterinary medical officers) generally exceeded 10 percent. The impact of FDA's personnel recruiting and retention problems may worsen over the next decade as about three-fourths of FDA's senior staff will be eligible to retire. (See pp. 29-31.)

Problems in Laboratories, Facilities, and Equipment

FDA's headquarters offices and laboratories, located in 23 facilities, are decentralized and dispersed across 7 sites throughout the Washington, D.C., area. General Services Administration (GSA) officials told GAO that FDA's laboratories have serious problems, including inadequate electrical, heating and cooling, and waste disposal systems. This can damage scientific equipment, can result in inaccurate test results, and has caused FDA to abandon experiments in progress. At FDA's laboratory facilities, GAO observed such problems as crowded space, leaking pipes, and damaged ceilings. (See pp. 32-35.)

In addition to problems in the laboratories, GAO observed crowded conditions in office space in FDA's Center for Drugs. Staff at all levels, including medical doctors and Ph.D. pharmacologists, statisticians, and chemists, were working in small, crowded offices. In many instances, the space occupied by FDA staff was far below the amount prescribed by GSA standards. In some cases, offices were so cramped that doors could only be partially opened. (See pp. 24-27.)

FDA maintains, and GSA agrees, that the most efficient way for FDA to carry out its mission is to consolidate its activities at one location, similar to a National Institutes of Health campus setup. FDA estimates that a consolidated campus would cost between $447 and $477 million, depending on the buildings already present at a given site. (See pp. 33-36.)

Regarding FDA's scientific equipment, GAO's analysis showed that FDA's equipment inventory originally cost about $80 million to purchase. Based on the government's replacement criteria, 29 percent of FDA's equipment should have been replaced by now. FDA reports that the use of obsolete equipment has also hampered its ability to conduct its work. (See pp. 36-38.)

Recommendations

To provide a more accurate basis for determining FDA's resource needs, GAO is making several recommendations to the Congress that will require FDA to make an agencywide assessment of its staffing, facilities, and equipment needs given specific budgetary and staffing levels. Due to the urgency of FDA's problems, GAO believes the agency should place a high priority on completing this assessment. Furthermore, FDA should prepare a timetable for the staffing, systems, and management changes it will implement as a result of its assessment. (See pp. 39-40.)

Agency Comments

GAO did not obtain official agency comments on this report. However, GAO did obtain the views of FDA officials and incorporated their views where appropriate. GAO also obtained the views of the food, drug, and medical device industries which are contained in chapter 5. (See p. 40.)

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Abbreviations

AIDS	acquired immunodeficiency syndrome
FDA	Food and Drug Administration
GAO	General Accounting Office
GSA	General Services Administration
HHS	Department of Health and Human Services
OMB	Office of Management and Budget
OPM	Office of Personnel Management
SES	Senior Executive Service

Introduction

The Food and Drug Administration (FDA) is a scientific regulatory agency that plays a vital role in assuring the safety of the nation's foods, drugs, medical devices, radiological products, and cosmetics.[1] Because of the wide range of products it regulates, FDA touches the day-to-day lives of virtually all citizens. FDA estimates that 25 cents of every dollar spent by consumers involves products regulated by the agency.

In a letter dated October 20, 1988, the Chairmen and Ranking Minority Members of the Senate Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies and the Senate Committee on Labor and Human Resources expressed concern over whether FDA has sufficient resources to meet its current responsibilities and whether it will have enough resources to meet increasingly complex future demands. In response to this request we developed information on FDA's staffing requirements; staff recruitment and retention rates; and laboratory, space, and equipment needs.

Background

FDA fulfills its regulatory responsibilities by (1) performing premarket evaluations of drugs and medical devices, (2) conducting safety reviews of food and drug products, (3) providing criteria for use in manufacturing products, (4) conducting post-market surveillance of approved products, and (5) taking enforcement action on products found to be not in compliance with federal standards. As part of its responsibilities, FDA investigates product tampering incidents, such as cyanide in Tylenol and Chilean grapes, and expedites reviews of drugs that deal with public health crises, such as the acquired immunodeficiency syndrome (AIDS) epidemic.

FDA is composed of a headquarters staff, supported by 6 regional offices, 21 district offices, and a national research center.[2] FDA's headquarters work is divided along product lines in five centers: the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Devices and Radiological Health, and the Center for Veterinary Medicine.

[1] FDA's basic authority is derived from the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.). FDA also has responsibilities under many other laws.

[2] FDA operates the National Center for Toxicological Research, which conducts research programs to study the biological effects of potentially toxic chemical substances found in the environment

The Office of Regulatory Affairs has administrative responsibility for FDA's field offices. These offices inspect domestic and imported products and domestic manufacturers, investigate product tampering, and supplement the centers' work in developing methods used to analyze samples of products.

FDA currently operates 19 field laboratories and 6 headquarters laboratories. The headquarters laboratories are primarily involved in developing methods to test products; the field laboratories do most of the testing.

In fiscal year 1989, FDA projects that it will operate at a level of 7,229 staff-years. The agency's fiscal year 1989 funding level was expected to total over $512 million.

Objectives, Scope, and Methodology

As identified in the request, and based on discussions with the requesters' staffs, we agreed to obtain and analyze available data and studies related to three areas: FDA's staffing requirements; staff recruitment and retention rates; and FDA's laboratory, space, and equipment needs.

We focused our review on FDA's headquarters and on the agency's three largest centers—the Center for Drug Evaluation and Research (the Center for Drugs), the Center for Food Safety and Applied Nutrition (the Center for Foods), and the Center for Devices and Radiological Health (the Center for Devices). Together these centers, along with FDA's field staff that perform center program activities, account for about 5,500, or 76 percent, of FDA's total staff and 68 percent of its fiscal year 1989 appropriation.

To obtain information on staffing and facilities, we reviewed FDA studies and estimates where available. We also interviewed over 40 FDA officials to identify issues related to the agency's resource requirements, planning, and allocation. Except for selected examples, FDA was unable to provide comprehensive data on staffing and recruitment trends. Therefore, our discussion of these issues relies primarily on interviews with FDA officials. The information they provided was not independently verified by GAO. To help assess the adequacy of FDA's facilities, we interviewed officials at the General Services Administration (GSA), the National Institutes of Health, and the Department of Commerce's National Institute of Standards and Technology. We also analyzed FDA's equipment inventory to determine the extent to which its scheduled replacement date was passed.

To obtain the views of industry and consumer groups on FDA's resources, we interviewed officials of the Center for Science in the Public Interest; the Grocery Manufacturers of America, Inc.; the Health Industry Manufacturers Association;[3] the Industrial Biotechnology Association;[4] the National Food Processors Association; the Pharmaceutical Manufacturers Association;[5] and the Nonprescription Drug Manufacturers Association.

Our work was performed from February to June 1989 in accordance with generally accepted government auditing standards. We did not obtain official agency comments on this report; however, a copy of the draft report was provided to FDA officials and we incorporated their comments where appropriate.

[3]The Health Industry Manufacturers Association represents firms manufacturing medical devices, such as artificial hips and contact lenses.

[4]The Industrial Biotechnology Association represents firms engaged in commercial biotechnology that develop pharmaceutical products through the use of genetic engineering.

[5]The Pharmaceutical Manufacturers Association represents research-based pharmaceutical firms manufacturing drug products.

FDA Estimates That It Needs a Major Increase in Staff

Since fiscal year 1980, FDA's legislatively imposed responsibilities have greatly increased. At the same time, it has had to deal with public health crises, such as the AIDS epidemic and product-tampering incidents, which have added demands on its resources. In spite of these increasing demands, FDA's staffing levels have declined over the past decade. At present, FDA officials estimate that a staffing increase of more than 2,000 positions is needed to restore positions lost since 1980 and to meet its new demands.

New Legislation Has Increased FDA's Responsibilities

During the 1980s, legislation was enacted that significantly increased FDA's responsibilities.[1] These new responsibilities cut across the range of FDA activities, from premarket review of drugs and medical devices to consumer education on food safety issues. For example the:

- Infant Formula Act of 1980 required FDA to establish regulations to assure the purity and presence of required nutrients in infant formula products as well as the maintenance of proper records by the manufacturers.
- 1983 Orphan Drug Act required FDA to adopt procedures to expedite the approval of drugs for rare diseases and conditions.
- 1983 Federal Anti-Tampering Act authorized FDA to investigate incidents of tampering with foods, drugs, devices, and cosmetics.
- National Childhood Vaccine Injury Act of 1986 required manufacturers to maintain records on the production, testing, and handling of childhood vaccines, and required FDA to perform studies on vaccines and permits FDA to recall those that were found to be hazardous.

In addition to these new legislative responsibilities, FDA has had to continue to meet its existing responsibilities under the Federal Food, Drug, and Cosmetic Act and other laws and devote resources to deal with emergencies, such as cyanide-laced grapes from Chile, food contamination resulting from the Chernobyl nuclear accident, and public health crises, most notably the AIDS epidemic. Biotechnological advances are also resulting in new and more complex types of products being submitted for FDA approval. During fiscal years 1980 through 1984, FDA's Center for Biologics Evaluation and Research received a total of 114 investigational new drug applications in the biotechnology area. During fiscal years 1985 through 1988, the number of such applications increased nearly four times.

[1] Appendix I briefly discusses new statutory requirements affecting FDA responsibilities.

As Demands Have Increased, FDA's Staffing Has Decreased

Even though FDA's legislative responsibilities have been significantly increased over the past decade, its staffing levels have declined since fiscal year 1980. As table 2.1 shows, FDA's staff declined from 7,816 in fiscal year 1980 to an estimated 7,229 in fiscal year 1989—a reduction of 587 (or 7.5 percent). The President's proposed fiscal year 1990 budget calls for a funding level of $513 million[2] to support a headquarters and field staffing level of 7,386. While the 1990 budget proposal would represent an increase of 157 staff over its fiscal year 1989 level, it would still be 430 or 5.5 percent fewer staff than FDA had in fiscal year 1980. The agency's funding level for fiscal year 1990 would be about $328 million in constant 1980 dollars, about 2 percent higher than its $321 million appropriation for fiscal year 1980.

Table 2.1: FDA Staffing Levels
(Fiscal Years 1980-89)

Fiscal year	Actual staffing level	Difference from prior year	Percent over/ under prior year
1980	7,816	•	•
1981	7,467	−349	−4.5
1982	7,085	−382	−5.1
1983	7,219	+134	+1.9
1984	7,172	-47	-.7
1985	7,094	-78	−1.1
1986	6,904	−190	−2.7
1987	6,855	-49	-.7
1988	7,103[a]	+248	+3.6
1989	7,229[b,c]	+126	+1.8
Net difference		**−587**	

[a]In fiscal year 1988, FDA received funding to support 127 staff-years for AIDS and devoted 278 staff-years for AIDS-related work.

[b]Estimated.

[c]FDA's fiscal year 1989 appropriation request was based on 323 staff-years being used for AIDS. FDA estimates that it will devote about 400 staff-years for such work in fiscal year 1989.

The changes in FDA's staffing levels are more significant when they are compared with the agency's estimated needs for each year. FDA's annual budget and staffing needs go through three levels of review within the executive branch—the Public Health Service, the Department of Health and Human Services (HHS), and the Office of Management and Budget (OMB), before being submitted to the Congress. FDA's staffing requests have been reduced by each review at the executive branch level, with

[2]This total includes approximately $413 million in direct appropriations and $100 million in non-federal sources (that is, user fees).

substantial reductions usually being made by OMB. Table 2.2 shows FDA's staffing requests for fiscal years 1982 through 1989 and its actual staffing levels. (Data for fiscal years 1980 and 1981 were not available.)

Table 2.2: FDA Staffing Requests and Actual Staffing Levels (Fiscal Years 1982-89)

Fiscal year	FDA staffing request	Actual staffing level	Difference
1982	8,578	7,085	−1,493
1983	7,636	7,219	- 417
1984	7,419	7,172	- 247
1985	7,477	7,094	- 383
1986	7,399	6,904	- 495
1987	6,944	6,855	- 89
1988	6,898	7,103	+ 205
1989	7,419	7,229[a]	- 190

[a]Estimated.

Comprehensive Analysis of FDA's Staffing Needs Conducted in 1975

FDA's last comprehensive assessment of its staffing needs was made in 1975, at which time it had projected a staffing need of 9,000 by 1982. FDA's staffing did not grow but instead declined significantly in the 1980s. FDA's 1975 analysis was designed to determine the agency's long-term staffing needs. FDA believed that such a study was needed to assess the level of resources required to reduce the risks to the public from the products it regulates.

In conducting the study, FDA used a variety of methodologies, ranging from sophisticated quantitative techniques, computer modeling, and zero-based budgeting. The study focused on 300 activities that FDA program managers identified as consuming an extensive amount of the agency's resources. FDA determined that 120 of these activities were of a high priority and needed an adequate level of support. FDA then used historical data to estimate its projected workload and calculated the staff-years needed to address its high-priority activities adequately for the next 5 to 7 years. For the lower priority activities and others that were not resource intensive, FDA determined that no increase in staffing was needed. FDA concluded that it would need over 9,000 staff by fiscal year 1982 to adequately meet its responsibilities.

FDA Action Planning Process Calls for a Comprehensive Resource Needs Assessment

In July 1984, FDA commenced an agency planning process that resulted 11 months later in the first FDA "Action Plan." This effort was described by the Commissioner as a "coherent statement of FDA's highest priorities. . .An invaluable mechanism for defining the agency's most urgent resource needs. . ." FDA said that while this planning technique resulted in a focused emphasis on a few top-priority resource needs, there was evidence that some of FDA's managers saw value in a more comprehensive assessment of FDA's needs. One of six internal task forces charged with giving "bottom-up" recommendations to FDA's senior managers examined the process of resource allocation in FDA.

The task force made a number of recommendations to improve FDA's efficiency and effectiveness. It recommended that the agency needed to determine which program activities should be increased, which should remain constant, and which should be reduced or eliminated. The task force's 1984 report found that FDA program managers were confronted with the dilemma of (1) increased demands for services and new technological advances in products and processes, (2) no decrease in responsibilities for ongoing activities, and (3) less resources to do the job. The strategy for coping with this situation was to often do "less of everything rather than stopping anything." The report concluded that with limited future prospects of additional resources for FDA, it was essential for the agency to take certain actions to improve the ways in which it managed resources.

The resource allocation task force also proposed that FDA consider using a zero-based approach in its program planning processes to prioritize projects and activities on an agencywide basis and across program lines. While FDA's existing planning process established priorities within programs, a broader approach was needed to consider priorities across programs, the report said, in order to assure that FDA's resources were devoted to the highest priority areas.

The task force further proposed that FDA use its resources more effectively, for example, by (1) better coordinating research among centers and the field; (2) distributing headquarters and field activities more efficiently, taking into account high-priority activities and the skills needed to accomplish them; and (3) reducing the traumatic effect of emergencies on resources by establishing special funds and personnel to deal with these situations.

Regarding potential areas for economizing, the task force considered several options to the way FDA was managing its resources. Since more

than two-thirds of FDA's budget was consumed in salaries and benefits, the task force focused on areas that would reduce the commitment of people. The areas for economizing included consolidating FDA's headquarters facilities and field laboratories, identifying and discontinuing activities that may no longer be necessary, and eliminating unnecessary layers of review. The task force made several proposals to improve FDA's management and recommended the need to conduct cost/benefit analyses for many of them.

The final area the task force reviewed related to identifying alternative sources of staff and funding for FDA. Among the alternatives considered were expanding the use of user fees to recoup FDA's costs for certain activities and reexamining ways of delegating more responsibility to industry or shifting work, where appropriate, to industry or other federal agencies. The task force proposed that FDA analyze and evaluate alternative mechanisms designed to improve industry submissions to FDA for review. The task force noted that both the industry and FDA waste staff time and resources on submissions that are inadequately prepared.

FDA Believes It Has a Serious Staffing Shortfall

FDA reported that only half of the recommendations made by the six internal task forces were incorporated into the design of the action planning process. Many of the recommendations of the resource allocation task force that related to comprehensive resource management were not implemented. However, in view of the continued increased demands on the agency, many of the proposals continue to be relevant. For example, the agency has not (1) assessed, on an agencywide basis, all of FDA's activities and determined which ones could be accomplished in the face of limited resources; (2) considered shifting work, where appropriate, to industry and other federal agencies to assist FDA in accomplishing its mandates; and (3) made a study to identify activities no longer necessary.

Center officials told us that the dilemma of making resource tradeoffs portrayed in the task force report continues today. These officials perceived continued increases in demands on their programs and reductions in resources to meet these demands. Officials of the centers for drugs, devices, and foods told us that the staffing shortfalls are causing serious problems for FDA. They reported that there has been inadequate attention given to some key activities. Factors that have contributed to this situation have been new legislatively imposed responsibilities; increases in the volume and/or complexity of products received from industry for

FDA approval; and new crises, such as the AIDS epidemic and food safety problems.

As an example of one crisis, beginning in the mid-1980s, FDA began to play an important role in the research, development, and approval of products used in the treatment and prevention of AIDS. As noted earlier in the footnotes on table 2.1, the level of FDA activity related to AIDS has substantially exceeded the level contemplated when appropriations were made. FDA information shows that in fiscal year 1988, FDA devoted more than twice the staff-years for AIDS work than it received funding to support. In fiscal year 1989, FDA expects to devote 77 more staff-years for AIDS than provided for by its fiscal year 1989 appropriation.

Problems relating to FDA's food programs also illustrate the difficulties a staffing shortfall causes. While the staffing levels allocated to these programs decreased from 2,569 in 1980 to 2,129 in 1989, FDA's responsibilities increased significantly; for example, it was assigned new legislative responsibilities under the Infant Formula Act of 1980 (see pp. 11 and 42) and the Pesticide Monitoring Improvements Act of 1988 (see p. 44). Under the pesticide legislation, the Center for Foods has to (1) implement a computerized data management system to collect information on and evaluate pesticide residue monitoring data and (2) enter into cooperative agreements with several countries exporting food to the United States. The center is also responsible for developing methods to analyze pesticide residues. According to the center, it has had the resources to develop analytic methods that can be used in field laboratories to test for only 150 of 450 approved pesticides on the market.

In addition to these new legislatively imposed responsibilities, the Center for Foods and related field staff have had to deal with increased concern over the safety of seafood (a growing part of the American diet); pesticide residues on fresh fruits and vegetables; illness outbreaks associated with food-borne pathogenic microorganisms (e.g., listeria and salmonella); and a variety of unplanned events, such as glass in baby food and, most recently, cyanide-laced grapes from Chile. The Chernobyl nuclear accident also required increased FDA inspections of imported foods from Europe and Asia to detect possible radiation contamination.

The Center for Devices is also experiencing a significant workload increase while facing constrained resources. The center's devices and radiological health programs have 1,287 staff-years for fiscal year

1989—only 40 more than it had in fiscal year 1980. To address its growing workload in the medical device area, the center has shifted resources away from radiological health compliance activities, product risk assessment and research, and health education programs. From fiscal year 1984 through fiscal year 1988, the number of staff-years devoted to radiological health activities declined from 333 to 194.

Even with this reallocation of resources, center officials report that they cannot implement all of the provisions required by statute. For example, the Medical Device Amendments of 1976 require FDA to develop performance standards on class II devices.[3] However, of an estimated 830 types of class II devices, no standards had been developed at the time we completed our work and only one was being developed. Center officials told us that the development of standards was resource-intensive in that an estimated 24,000 staff-years would be required and that they have not had the staff to do this work.[4]

According to the center, the reduction of staff in radiological health activities has also left this area at "minimum sustainable levels" and has reduced enforcement of radiation performance standards for such items as X-ray machines, lasers, and microwave ovens. In addition, officials reported reduced scrutiny of manufacturers' quality control and testing reports, fewer inspections of manufacturers' plants, and fewer enforcement actions.

FDA Reports Needing a Staffing Increase of Over 2,000

FDA officials told us that they need a significant increase in staff resources in 1990 in order to meet all of the agency's responsibilities. Since FDA's last comprehensive study of its staffing needs was conducted 14 years ago—in 1975—we asked FDA officials to provide us with data on their staffing requirements for fiscal year 1990.

[3]There are three classes of medical devices based on safety and effectiveness standards. The 1976 amendments require FDA to establish performance standards for class II medical devices. A class II device is one for which the existing controls in place are insufficient to provide a reasonable assurance of safety and effectiveness and for which scientific information exists to develop a performance standard to provide such assurances.

[4]An FDA official stated that the center expended 30 staff-years on each of its previously developed standards for radiation equipment. She said that since medical devices are more complex, development of a device standard will require at least the same number of staff-years. On this basis, 24,900 staff-years would be required to develop the standards for the 830 types of class II devices.

Partial data on staffing requirements were available from the Center for Drugs. The center has estimated that it would need twice as many medical reviewers as it currently has to process new drug applications within the 180-day requirement of the Federal Food, Drug, and Cosmetic Act. Currently, the average processing time for new drug applications is 31 months. The estimated need for additional medical reviewers is derived from an analytical model developed by the center to estimate the number of staff needed to review new drug applications. The model uses projected workloads of product submissions, the length of time it takes to review products, and existing backlogs to estimate the number of medical reviewers it needs. The center reports that adding more medical reviewers would also require additional staff to support the work of the reviewers, including pharmacologists, chemists, and pharmacists.[5]

Agencywide, FDA estimated that it needed over 2,000 positions above its current allocated staffing levels to (1) replace those lost since 1980, (2) fully implement new legislative requirements, and (3) handle responsibilities related to AIDS and the regulation of medical devices. This would give FDA a staffing level of about 9,200. FDA officials said, however, the 2,000 positions would not allow FDA to expand its inspections of seafood and imported products or to address biotechnological advances that are resulting in new types of products being submitted for FDA approval. The President's budget for fiscal year 1990 provides funding for a staffing level of 7,386, which would still be about 1,800 below FDA's estimated staffing needs.

We found it difficult to substantiate FDA's estimate of its need for at least 2,000 more staff because FDA lacks uniformity in its internal management information systems. Its estimate was based on partial information compiled from the judgmental estimates of senior FDA officials and from a variety of center and field office time and activity reporting systems. Data from these systems are used to help manage the use of FDA's available resources. FDA does not, however, maintain a centralized system to allow it to determine total agency resource needs on an ongoing basis. The various systems are not linked in a way that supports the preparation of a comprehensive assessment of current and future staffing needs.

[5]Center officials estimated that they would need an increase of at least 460 positions over current staffing levels. For fiscal year 1990, FDA's budget justification to the Congress proposed a total staffing level of 2,142 for the Center for Drugs and its field office activities. This would represent a staffing increase of 84 positions from its fiscal year 1989 level of 2,058.

A more effective method for estimating human resource needs would be based on a variety of factors, including anticipated workload and productivity levels. However, FDA lacks a method for routine recording of staff time charges to determine the amount of time it takes to perform various activities and to properly forecast staffing requirements. To be consistent with the Standards for Internal Controls in the Federal Government, published by GAO in 1983, FDA should account for staff-years used in a manner that allows actual usage to be reported by program or activity. There are automated time accounting systems in the Office of Regulatory Affairs and the Center for Foods. Other centers we visited do not have such automated systems but instead relied on a variety of manual reporting techniques.

If FDA had more comprehensive documentation of its staff time charges, and better integrated such data at an agency level, we believe it could more reliably determine (1) the current level of resources being applied to different activities, (2) how long specific activities take, and (3) whether these expended resources match FDA's priorities. Such a system would also support the preparation of a comprehensive agencywide assessment of current and future staffing requirements.

Problems With Recruitment and Retention of Scientists at FDA

FDA reports that it has experienced considerable difficulty over the past 5 years in filling senior-level positions. FDA officials cite pay disparities between the federal government and the private sector and cramped and inadequate office space as contributing factors to this problem. High employee turnover is also affecting productivity and raising concerns about potential quality issues.

Difficulties in Filling Senior Positions

FDA does not maintain centralized data that would allow us to analyze its overall recruiting experiences for professionals. At our request, FDA compiled data on the time it took to recruit and fill certain vacant positions at the Senior Executive Service (SES) level. FDA also provided additional information on its difficulties in recruiting for specific positions.

FDA's data showed that during the last 6 years, 36 of 64 senior executive positions were vacant for lengths of time ranging from at least 4 months to more than 5 years. Vacant positions existed in all six FDA centers and the Office of Regulatory Affairs, including positions at the directorate, deputy directorate, and associate commissioner levels. Fifteen of these 36 positions were vacant for less than 1 year before they were filled. Most of the other 21 positions were vacant for up to 2 years; and one, a Division Director position in the Center for Drug Evaluation and Research, has not been permanently filled for over 5 years. FDA has been unable to recruit a qualified individual for this position, and the position has been filled on an acting basis. Table 3.1 shows the vacant senior executive positions in each of the three FDA centers included in our work.

While FDA data showed a large number of vacancies, sufficient information on the nature and extent of active recruiting efforts and problems encountered were not readily available. Therefore, we cannot draw any firm conclusions on the extent to which pay or other factors affected FDA's vacancy rate.

Table 3.1: Length of Time to Fill Senior Executive Vacancies in Three FDA Centers (6-Year Period Ending Aug. 24, 1989)[a]

Center/position title	When vacant	When filled	Time vacant
Center for Drug Evaluation and Research:			
Director, Division of Epidemiology and Surveillance	11/13/83	Not filled	5 yrs., 9 mos.
Director, Division of Generic Drugs	08/28/86	08/02/87	11 mos.
Director, Division of Biopharmaceutics	01/21/83	05/25/86	3 yrs., 4 mos.
Director, Division of Cardio-Renal Drug Products	08/05/84	06/22/86	1 yr., 10 mos.
Deputy Director, Office of Drug Evaluation II	06/16/88	06/04/89	12 mos.
Director, Office of Management	12/01/87	Not filled	1 yr., 8 mos.
Director, Division of Gastrointestinal and Coagulation Drug Products	01/22/87	10/29/87	9 mos.
Director, Division of Surgical-Dental Drug Products	05/29/87	Not filled	2 yrs., 3 mos.
Director, Division of Anti-Infective Drug Products	06/06/88	Not filled	1 yr., 2 mos.
Center for Food Safety and Applied Nutrition:			
Director, Office of Compliance	03/16/86	08/02/87	1 yr., 4 mos.
Director of Center	07/18/87	Not filled	1 yr., 9 mos.
Director, Office of Toxicological Sciences	05/22/88	Not filled	1 yr., 3 mos.
Center for Devices and Radiological Health:			
Director, Office of Science and Technology	12/04/86	10/11/87	10 mos.
Deputy Director, Office of Science and Technology	12/04/86	12/18/88	2 yrs.
Director, Office of Device Evaluation	11/30/88	07/16/89	8 mos.
Deputy Director, Office of Device Evaluation	12/04/86	10/09/88	1 yr., 10 mos.
Director, Office of Management Services	01/26/89	Not filled	7 mos.

[a]Senior executive vacancies represent only positions for which FDA issued a formal vacancy announcement and recruited. The date of vacancy and the formal announcement of that vacancy do not necessarily coincide.

Source: Food and Drug Administration

Pay Disparities May Contribute to Problems

FDA officials said that disparities in pay between the federal government and the private sector have adversely affected FDA's recruitment efforts. Officials at the Center for Drugs cited its efforts to recruit a division director. After the person occupying the position advised FDA in 1987 that he planned to leave the agency in the following year, a committee was formed in the spring of 1988 to identify candidates for the position.[1]

[1]Although the position became vacant in June 1988, a formal vacancy announcement was not issued by FDA until April 13, 1989.

Letters were sent to about 20 individuals that the committee considered to be highly qualified.

While some candidates responded by stating that they were not interested in leaving their current positions, FDA officials told us that some also said they could not afford to consider the FDA position. An FDA report described the case of one candidate who was an associate professor of medicine at an eastern university. Despite being interested in the position, the candidate withdrew his name from consideration because of (1) the disparity between his present university salary ($91,200) and FDA's salary offer (about $76,000); (2) the loss of other university-provided benefits, such as health insurance and retirement, which he would have to pay for himself as a federal employee; and (3) the significantly higher cost of living in the Washington, D.C., area. This position was unfilled as of August 1989.

FDA officials believe that the quality of candidates applying for positions with FDA is lower than that of the private sector because of the wide disparities in salary and benefits. FDA officials also noted that this poses a serious recruiting problem because of a shortage nationally of experienced senior managers.

Although FDA did not maintain data on its recruitment efforts for lower level scientific positions, FDA officials said that these efforts were similarly hindered, in part, by the inability to offer salaries and other benefits competitive with academia and industry. Officials at the Center for Foods, for example, reported that recruiting for scientists in needed specialties, such as organic and pesticide chemistry, immunochemistry, and nuclear magnetic resonance spectroscopy, was difficult because of the (1) inability to offer competitive salaries, (2) scarcity of qualified applicants, and (3) lack of direct authority for FDA to hire applicants, which frequently resulted in hiring delays and the subsequent loss of candidates.[2] In one case, the center said that it took 3 years before it could recruit a microbiologist trained in dealing with a certain type of foodborne pathogen that causes botulism.

[2]When an agency does not have authority to hire directly, it generally must use the Office of Personnel Management's (OPM's) process for certifying and hiring candidates, which FDA says can take from several weeks to a few months. FDA reports that, until recently, it had authority from OPM to hire directly only medical officers and certain grades of biomedical engineers and mathematical statisticians without OPM certification. In April 1989, OPM delegated further authority to FDA to directly hire biologists, chemists, and microbiologists when it can document a history of severe recruitment problems.

FDA also noted similar difficulties in hiring biostatisticians for several of its centers. A 1988 FDA study found that one center had not recruited a new graduate Ph.D. in biostatistics or mathematical statistics in over 10 years, in spite of several attempts to do so. FDA told us that one reason it is unable to recruit biostatisticians was the large difference in starting salary that FDA could offer (about $27,000) in comparison to an average starting salary for an assistant professor of biostatistics at a university (about $40,000). Other reasons cited by FDA included the limited potential for advancement and the lengthy hiring process cited earlier.

FDA's Staffing Problems May Worsen

In 1988, a conference sponsored by the Food, Drug, and Law Institute reported on future issues confronting FDA. One panel, composed of experts in human resource management from the public and private sectors, including congressional staff, representatives from the industries regulated by FDA, and staff from FDA and OMB, studied FDA's future staffing needs.

The panel concluded that FDA is likely to have an increasingly difficult time in recruiting and retaining staff, especially those with specialized expertise, due to low salaries. The report also noted that FDA may need a different mix of personnel in the future, with more reliance on specialists who are highly trained in technically sophisticated areas. According to the study, because FDA will have difficulty attracting these highly specialized staff, it will need to create special incentives for such people to work at the agency. If FDA is unable to recruit the people it needs, it may have to enter into more contracts with universities to find other sources of personnel and to form new relationships with other government agencies.

The report noted that FDA may also have to (1) adopt its own pay system, including special pay scales for "hard-to-reach" disciplines with geographical pay adjustments, and (2) perform more in-house education to provide its staff with the expertise needed. In addition, the report raised the concern that unless FDA's staffing difficulties are adequately dealt with, the quality of FDA's staff may deteriorate, and "Serious mistakes may be made,... For example, a product with an unrecognized side effect may be allowed on the market, or a major outbreak of food poisoning could occur."

According to FDA's May 1989 Action Plan, the agency is taking some initiatives to improve staff recruitment, including requesting further authority from the Office of Personnel Management to allow FDA to hire

certain specialties directly and to offer special pay rates for AIDS-related positions. In addition, FDA said that it received authority from OPM to contract with private recruiters to help obtain certain medical and scientific specialties and from HHS to offer cash awards ranging from $100 to $500 to agency employees to actively recruit for hard-to-fill positions. FDA has also hired a senior scientist from a private drug company on a part-time basis to develop a recruiting and training program for medical reviewers.

Inadequate Facilities Contribute to Recruiting Difficulties

Officials from the Center for Drugs reported that space shortages have also led to recruitment problems at senior and other levels. For example, the center said that it aggressively recruited a leading researcher for one of its vacant division director positions but the individual declined the offer due to cramped office space and a lack of laboratory facilities. Similarly, a physician who left the center for a job in the private sector cited cramped facilities as a reason for leaving.

We toured the office space occupied by personnel assigned to three divisions in the Center for Drugs having responsibility for reviewing neuropharmacological, oncologic, pulmonary, anti-inflammatory, and anesthetic products. Staff at all levels occupied this space, including SES and general schedule employees and commissioned officers of the Public Health Service, including medical officers; Ph.D. biostatisticians, chemists, and pharmacologists; and consumer safety officers.

In general, the center staff were working in offices that ranged in size from 62 to 179 square feet. In some cases, staff were sharing small offices, and in one instance the center's SES-level deputy director was forced to share space with two other employees. The crowded working conditions were made worse by the need for center staff to handle voluminous amounts of material submitted with drug applications (see fig. 3.1). Some offices we observed were so cramped that doors could only be partially opened. Figures 3.2 and 3.3 depict the office conditions we found in the three divisions of the Center for Drugs we toured.

General Services Administration regulations allow different size office space based on grade level and position. Space allowances range, for

example, from 100 square feet for GS-12 and 13 nonsupervisory positions to 400 square feet for senior-level supervisory positions.[3] However, FDA staff in the offices we toured generally had substantially less space than allowed under GSA standards.

Table 3.2 shows the amount of office space provided to selected professional and supervisory personnel in this center.

Table 3.2: Office Space Sizes for Selected Center for Drugs Personnel (June 1989)

Figures in square feet

Grade	Position	Office size	GSA allowance per employee
SES	Deputy Director of Center—shares office with special assistant and director of another center office	350	300–350
SES	Director, Office of Management for Center—shares office with Deputy Director	250	300–350
SES	Division Director, M.D.	174	300–350
GS-15	Medical Officer, M.D.	128	150
GS-15	Medical Officer, M.D.	94	150
GS-14	Pharmacologist, Ph.D. (supervisory)	120	225
GS-13	Chemist, Ph.D.	62	100

Retention of Certain Specialties Difficult

Employee retention is also a critical issue to FDA because retention has an impact on recruitment, orientation, and training costs as well as the continuity and stability of programs. Our analysis of FDA's data for nine critical scientific specialties showed that for certain specialties, FDA turnover rates were higher than the governmentwide rates.[4] While a variety of ways exist to measure employee turnover, the most widely used measure expresses employee separations over a specified period as a percentage of the average number of employed staff for that period. Using this measurement, rates may be developed for different types of separations, with the "quit rate" being the most often cited.[5]

[3]Under Presidential Executive Orders 12411 and 12512, GSA issued temporary regulations to accomplish cost-effective space reduction in the federal government. Under these regulations, federal agencies, by the end of fiscal year 1990, must reduce their work areas to an average of 135 square feet or less of space per employee.

[4]FDA informed us that nine specialties were critical to the conduct of its work—biologists, biomedical engineers, chemists, mathematical statisticians, medical officers, microbiologists, pharmacologists, physicists, and veterinary medical officers. We analyzed turnover data from OPM only for these specialties.

[5]Quit rates represent all employee resignations from the government, including those taking jobs in the private sector or returning to school.

Figure 3.1: Example of a New Drug Application—Center for Drugs

One copy of a large new drug application from a single firm contributes to crowded office space
Source: FDA photo taken during GAO tour of FDA facilities.

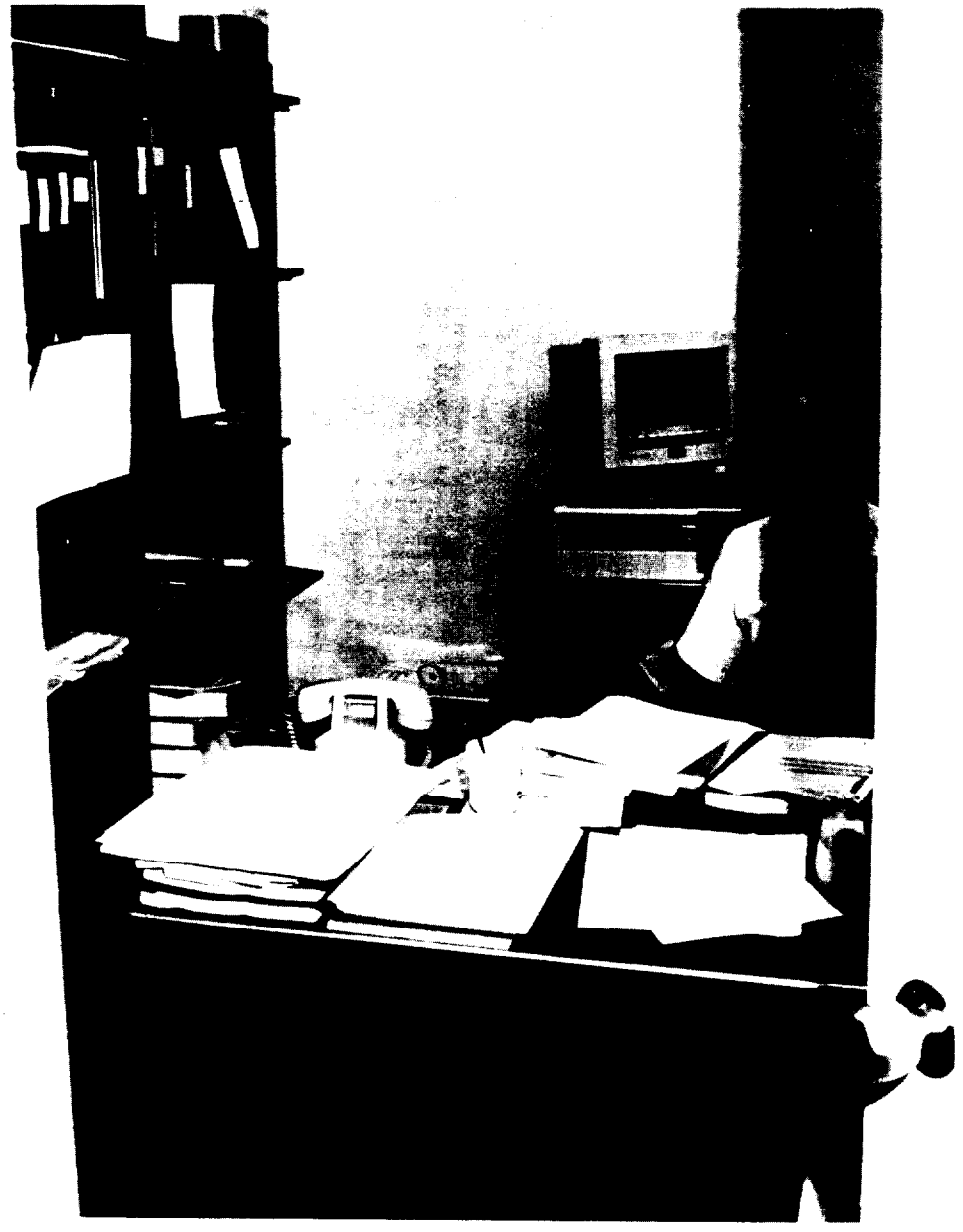
We compared FDA's quit rates with governmentwide data provided by OPM for fiscal years 1985 through 1987 in order to determine whether

Figure 3.2: Crowded Office Conditions—Center for Drugs

Example of crowded conditions in the office of a medical officer, M.D. (GS-14) - 94 square feet
Source: FDA photo taken during GAO tour of FDA facilities.

FDA was experiencing more significant problems than the rest of the federal government. (OPM data were not available for fiscal year 1988.) As shown in table 3.3, in many instances FDA's quit rate was higher than the governmentwide rate for most of the nine specialties. For example, in

Figure 3.3: Crowded Office Conditions—Center for Drugs



Example of crowded conditions in the office of a Ph.D. chemist, (GS-13) - 106 square feet
Source: FDA photo taken during GAO tour of FDA facilities.

fiscal year 1985, FDA's quit rate for biomedical engineers was nearly three times the governmentwide rate, and in fiscal year 1987, FDA's quit rate for pharmacologists was more than twice this average. FDA also experienced higher quit rates for several other specialties.

Table 3.3: Quit Rate Comparisons of FDA and Federal Civilian Employees for Selected Scientific Occupations (Fiscal Years 1985-88)

Figures in percents

	Quit rate							
	FY 1985		FY 1986		FY 1987		FY 1988	
Occupation	FDA	Federal	FDA	Federal	FDA	Federal	FDA	Federal[a]
Biologist	5.7	1.9	1.9	1.7	8.0	2.1	6.3	•
Biomedical engineer	12.5	4.3	12.5	6.0	3.7	4.5	2.4	•
Chemist	1.3	2.3	2.5	2.4	3.1	2.7	3.1	•
Mathematical statistician	2.1	4.0	6.7	3.7	6.3	2.1	1.8	•
Medical officer	5.4	4.8	10.8	5.2	3.2	5.9	4.7	•
Microbiologist	1.1	2.5	2.1	2.3	3.9	3.4	3.7	•
Pharmacologist	.9	2.0	.8	1.6	9.6	4.6	2.7	•
Physicist	0	2.6	7.4	2.4	4.0	1.9	0	•
Veterinary medical officer	1.7	1.4	0	1.7	2.0	1.6	2.0	•

[a]Not available.

Source: GAO analysis based on FDA and OPM data.

Turnover Rates Contribute to Problems

Using a broader definition of employee turnover, which included retirements and deaths, we analyzed FDA's data and found that the agency had lost about 20 percent of its medical officers from fiscal years 1985 through 1988. FDA's loss rates for medical officers were substantially higher than governmentwide rates (see table 3.4). FDA's loss rates for the other specialties ranged from about 2 percent for microbiologists in fiscal year 1985 to nearly 17 percent for pharmacologists in fiscal year 1987. Of increasing significance is the fact that FDA's turnover rates for six of the nine specialties were higher in fiscal year 1988 than in fiscal year 1985.

Table 3.4: Turnover Rate[a] Comparisons of FDA and Federal Civilian Employees for Selected Scientific Occupations (Fiscal Years 1985-88)

Figures in percents

	Turnover rate							
	FY 1985		FY 1986		FY 1987		FY 1988	
Occupation	FDA	Federal	FDA	Federal	FDA	Federal	FDA	Federal[b]
Biologist	10.2	5.5	7.5	6.0	14.3	5.8	14.5	•
Biomedical engineer	12.5	8.1	12.5	14.2	7.4	6.0	12.2	•
Chemist	3.5	6.4	6.7	6.6	6.6	7.2	7.8	•
Mathematical statistician	6.4	7.6	15.6	7.0	6.3	3.9	3.6	•
Medical officer	18.3	9.3	22.0	12.5	18.3	12.7	19.8	•
Microbiologist	2.2	6.8	7.5	7.0	11.2	7.0	9.3	•
Pharmacologist	4.6	5.2	3.4	3.6	16.7	10.3	13.5	•
Physicist	7.4	6.0	14.8	6.2	4.0	5.1	.0	•
Veterinary medical officer	5.2	7.0	13.5	8.9	11.8	7.3	17.6	•

[a]Defined as all separations (including retirements and deaths).

[b]Not available.

Source: GAO analysis based on FDA and OPM data.

FDA officials report that the loss of highly skilled staff without adequate backup personnel on board to take over can hamper FDA's work. For example, according to a 1988 FDA study, the turnover rate for medical officers in the Center for Drugs can translate into significant delays in the drug review process due to (1) the length of time it takes to fill a vacant position and train a new reviewer (6 months to 2 years to bring a new employee to an acceptable level of responsibility) and (2) the loss of full capability in a particular drug specialty when the sole reviewer in that area leaves. FDA officials noted that similar problems result from employee departures in other scientific disciplines.

As in the case of recruitment, FDA often cited disparities in salary as a reason for employee turnover. A 1987 FDA study, for example, compared salaries for FDA toxicologists[6] with similar positions in industry. The study found that industry salaries were 31 percent higher at the FDA entry level (a GS-11, Ph.D.), 25 percent higher at the senior management level, and about 40 percent higher for senior executive equivalent positions. Our review of other internal and external studies of FDA's personnel completed in 1987 and 1988 showed that factors other than pay contribute to retention problems. A report on biostatisticians attributed

[6]Toxicologists are not grouped together in a single occupational series and cut across several disciplines used by FDA.

losses in this occupation to the lack of nonsupervisory GS-14 positions, the attractiveness of salaries in private industry, and lack of scientific recognition. A study of losses of toxicologists identified factors relating to job satisfaction, such as the need for more diversified assignments.

High Percentage of FDA's Staff Expected to Leave or Retire

The projected loss of top managers is seen by FDA as an especially critical problem. These individuals often handle the more complex cases in the agency's workload. In 1987, FDA conducted a survey, which found that the median age of its top managers was 48 and that an estimated 74 percent of them are expected to leave the agency by 1997. The Center for Foods ranks high among FDA's organizations in the proportion of top managers expected to leave the agency. About 78 percent of these managers are expected to leave FDA by 1997. If the many managers eligible for retirement over the next decade exercise that option, FDA could be facing major leadership gaps given its current difficulties in filling vacancies.

FDA's Headquarters Laboratory, Space, and Equipment Needs

FDA's laboratories are in poor repair and have serious problems in their electrical, heating and cooling, and waste disposal systems. These continuing problems, as well as inefficiencies caused by having headquarters facilities located at seven different sites, led FDA to prepare a plan to construct consolidated facilities on a new campus at an estimated cost of about $500 million. GSA officials support FDA in its efforts to consolidate its facilities.

FDA also reports that much of its scientific equipment is old and not "state-of-the-art," which further hinders its efforts to test and regulate products. Our analysis of FDA's equipment inventory showed that 29 percent of the agency's scientific equipment, with an original purchase cost of $80 million, had reached its replacement date based on equipment life expectancy criteria established by the government.

Problems With Adequacy of Research Facilities

FDA's headquarters offices and laboratories are located in 23 facilities in 7 locations throughout the Washington, D.C., area.[1] A 1976 FDA study of the adequacy of its headquarters research facilities found that many were severely deficient. The study compared FDA's headquarters laboratories with standards reflecting the characteristics of newly constructed government, university, and private sector laboratories. The comparison disclosed that four of the agency's nine laboratories were "unacceptable," three were "marginal," and the other two "suitable" but with some marginal characteristics. Some of the problems included structural flaws, inadequate air handling and air contamination, and plumbing problems. In 1980, laboratories at the Center for Foods failed a FDA "good laboratory practices" inspection. One of the contributing factors was the inadequate conditions of the facilities. According to center officials, conditions have worsened since then, and two of the laboratories have been closed and another will be closed.

GSA officials responsible for acquiring and maintaining facilities for FDA and other agencies told us that at present, FDA laboratories continue to have serious problems with electrical, heating and cooling, and waste disposal systems. Inadequate laboratory facilities were cited by FDA officials as a major problem for two of the three centers included in our

[1] In these facilities, consisting of office and laboratory space, FDA employees (1) review new drug applications; (2) develop new methods to detect pesticide residues and the presence of microbial contaminants, such as salmonella and listeria, in food; (3) evaluate the effects of medical devices and radiological health equipment on the body; and (4) conduct work on AIDS-related activities, such as testing rubber gloves used in medical practice.

work, the Center for Foods and the Center for Devices. We visited these centers' laboratories.

Center for Foods officials told us there are serious problems with the heating, ventilation, and air-conditioning systems in the center's main laboratory building (Federal Office Building 8). The officials said that the temperature and humidity cannot be adequately controlled, which can compromise testing activities. High temperatures and humidity can lead to automatic shutting off of scientific equipment, resulting in ruined experiments and erratic measurements by such equipment used to test food products and color additives. We observed other problems, such as crowded laboratory space, leaking pipes, and damaged ceilings.

Another problem cited by center officials is inadequate air filtering by the central system, allowing particles of dirt to drift onto work areas and products being tested, which can affect test results. In addition, leaking water pipes have damaged expensive instruments, and contamination of the distilled water supply has impeded the conduct of research. As a result, makeshift devices (such as plastic hoods) are used to cover equipment, and research work that is contaminated has had to be repeated.

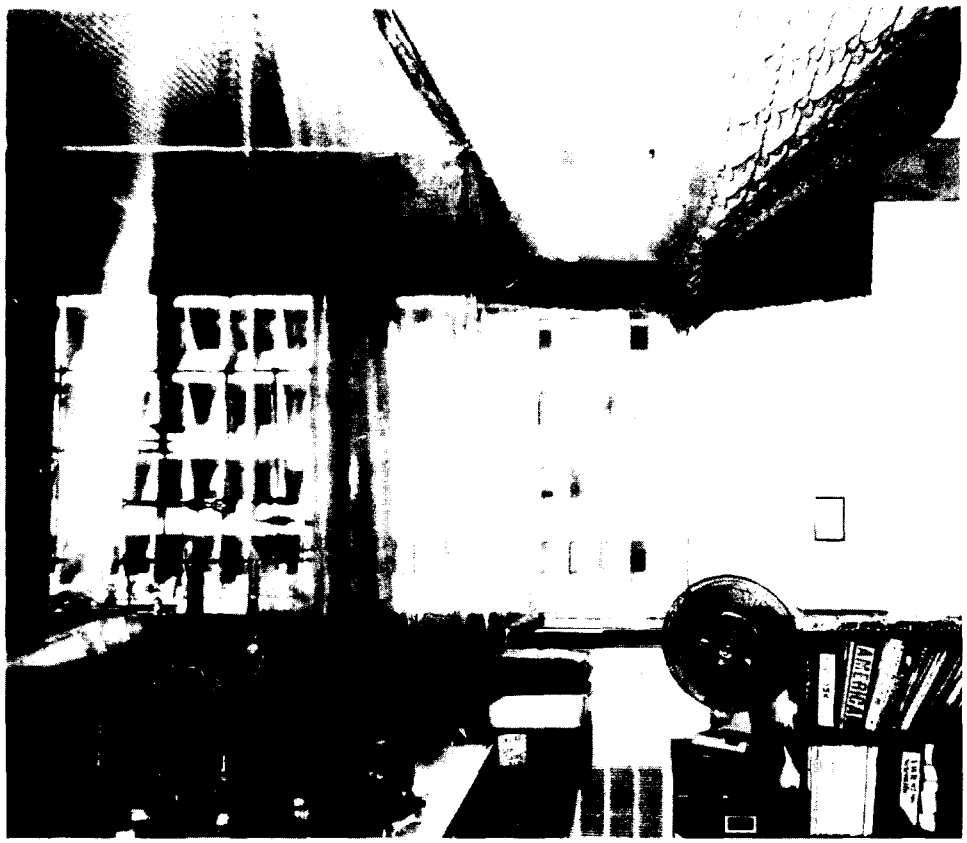
A 1988 GSA study estimated that $84 million would be needed to properly renovate the center's main laboratory facility. Specifically, the plumbing and electrical systems need to be replaced, as do the heating, ventilation, and air-conditioning systems. Figures 4.1 and 4.2 show some of the conditions we observed in the Center for Foods laboratories.

Similar problems exist at the laboratory facilities used by the Center for Devices. At one facility, which was not initially intended to serve as a laboratory, but as a light industry plant, center officials said that the poor design and age of the heating, ventilation, and air-conditioning system caused the center to abandon experiments in progress because of concerns that test results would be unreliable.

FDA Studies Recommend Consolidation of Facilities

The FDA Commissioner expressed concern over the inadequacy of the agency's office and laboratory space in recent testimony before the House and Senate Appropriations Committees. In particular, the Commissioner noted instances of overcrowding that has delayed FDA's hiring of staff. To overcome this obstacle, FDA has requested authority from OPM to allow staff to work part time at home.

Figure 4.1: Laboratory Space—Center for Foods

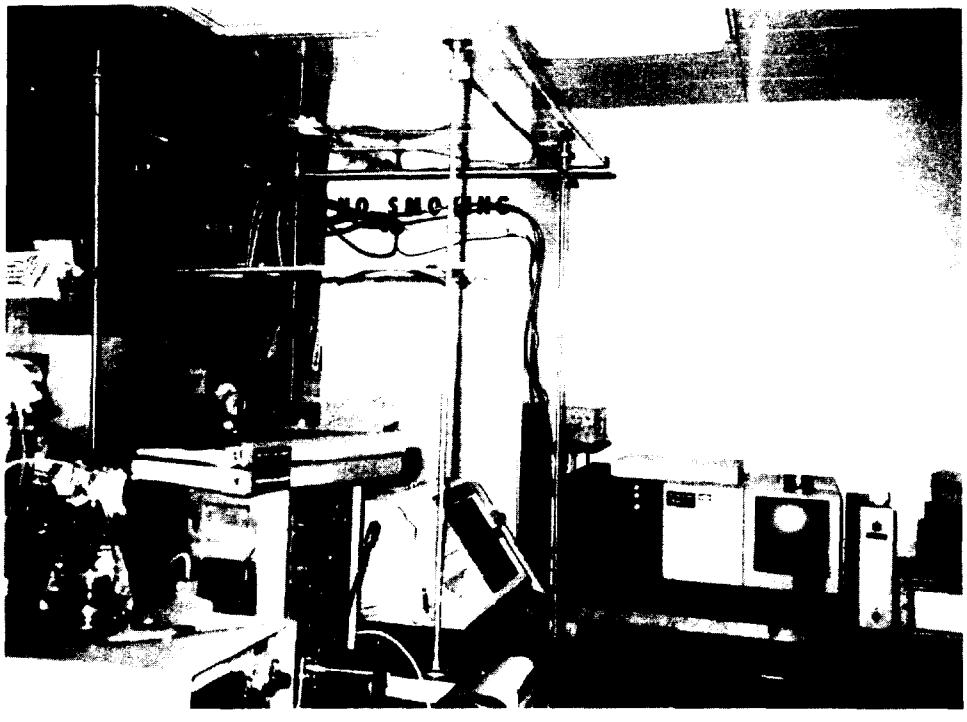


Air filter and plastic hoods used to prevent contamination of tests.
Source: FDA photo taken during GAO tour of FDA facilities.

The long-standing problems of inadequate space led FDA to assess the feasibility of consolidating its facilities on a unified campus. Both the National Institutes of Health and the National Institute of Standards and Technology operate out of a single location. Officials from these two agencies believe this has both simplified interactions between scientists and researchers on work crossing organizational lines and eliminated duplication of support services.

Various FDA studies since the 1960s have recommended the consolidation of FDA activities in newly constructed facilities. In the latest study, completed in April 1989, FDA prepared a 10-year facilities plan that considered whether it would be more cost effective to renovate FDA's existing facilities than to construct new facilities. The study noted the GSA estimate of $84 million needed to refurbish just one building housing

Figure 4.2: Laboratory Space—Center for Foods



Plastic shield protecting equipment from water and dust particles.
Source: FDA photo taken during GAO tour of FDA facilities.

the Center for Foods laboratories as a modern state-of-the-art facility. The study recommended that all headquarters facilities be consolidated at a single campus in Maryland. The costs of design and construction to achieve consolidation were estimated to range from $447 to $477 million, depending on the number of existing buildings already present at a given site.

The 1989 FDA study concluded that the fragmentation of the agency's facilities had hindered consultation between product reviewers and researchers. It found that as a result, FDA reviews of premarket applications for medical devices, drugs, biological products, and food additives took longer and were of lower quality.

GSA officials agreed that the consolidation of activities at one location is the most efficient way for FDA to carry out its activities. However, a GSA facilities planning official stated that when an agency prepares a plan for consolidation, he expects it to include (1) data on projected agency requirements in terms of personnel and whether its activities will grow

or decline; (2) cost-benefit analyses, to determine whether it is more economical to lease or purchase facilities; and (3) an evaluation of whether available government-owned facilities could satisfy FDA's needs.

The preparation of such information is included in OMB's Circulars A-11 and A-104. However, FDA's draft plan includes only changes in personnel. FDA officials told us that they recognize the need to include such information in its consolidation proposals and will do so as the project progresses. Further, they said that the intent of this early proposal was to obtain GSA's views on the merits of the project. FDA and GSA are discussing the plan, and FDA is planning to submit a requested report on the issue of consolidation to the Subcommittee on Agriculture, Rural Development, and Related Agencies, Senate Committee on Appropriations. As of August 21, 1989, the report had not been submitted.

Much FDA Equipment Has Reached Replacement Age

FDA officials told us that much of FDA's scientific equipment is old and outmoded, thereby hindering agency efforts to assure the safety of products. Our analysis of the scientific equipment inventory showed that the agency's equipment had an original purchase cost of $80 million; 29 percent of this equipment has already reached its replacement date. This date is based on life expectancy criteria established by the federal government. FDA did not have an estimate as to what it would cost to replace this equipment or information on the overall impacts on its work resulting from the use of equipment that should have been replaced. Table 4.1 shows the extent to which FDA's scientific equipment has passed its expected useful life.

Table 4.1: Extent of FDA Scientific Equipment With Replacement Dates of 1989 and Before

Dollars in thousands

Period	Pieces of equipment	Acquisition cost	Percent of cost
1974 and before	324	$304	[a]
1975 through 1979	1,274	1,567	2
1980 through 1984	2,756	5,451	7
1985 through 1989	4,366	16,038	20
Total reached replacement date	**8,720**	**$23,360**	**29**
Total scientific equipment	20,969	$80,372	100

[a]Less than 1 percent.

The adequacy of research equipment was a concern at two of the centers we visited—the Center for Foods and the Center for Devices. Officials at both centers said that the use of older equipment significantly

delayed such activities as testing for the presence of contaminants in food products and establishing guidance for approving medical devices. According to the centers, major increases in resources would be needed to acquire and maintain needed equipment. Although the third center, the Center for Drugs, also conducts research using scientific equipment, it did not respond to our requests for information on characteristics of its current equipment inventory. Information provided by the other two centers is presented below.

The Center for Foods—The acquisition cost of the center's current equipment inventory is about $15.4 million, with an estimated present value of nearly $20 million. According to the center, 25 percent of this equipment is past its scheduled replacement date, according to life expectancy criteria established by the federal government.

Center officials said that budget reductions severely limited the purchase of equipment during the last 10 years and that purchases of scientific equipment have averaged about $1 million annually. To keep up with technological advances and avoid obsolescence, these officials believed that state-of-the-art equipment should be purchased about every 5 to 7 years. Based on this assumption, center officials believe that their equipment budget should be three times the current level of expenditures.

Center officials told us that the current lack of state-of-the-art equipment lengthens the time it takes to conduct studies on food additives and chemical residues and to develop analytical methods for testing pesticides and chemical contaminants in foods. For example, modern mass spectrometric instrumentation has a greater sensitivity than current FDA instrumentation for detecting organic compounds, such as dioxin residues, that are found in milk packaging products. With a modern mass spectrometer, the center estimates that it could detect such compounds with fewer resources and in less time than currently required. The center estimated that such equipment would cost about $600,000.

According to the center, its budget for equipment maintenance has also been less than what is needed. The center budgeted $386,000 for fiscal year 1989 maintenance costs for scientific equipment, but officials estimate that $4 million is needed. To compensate for the lack of maintenance funds and laboratory technicians, officials report that center scientists must spend part of their time "troubleshooting" and personally making equipment repairs.

The Center for Devices—Officials at this center also told us that they have not had adequate funds to replace and maintain scientific equipment. During the last 10 years, the average amount spent on equipment has been about $830,000 per year. According to the center, about $2.7 million is needed this year to replace equipment past its life expectancy and to obtain state-of-the-art equipment.

Officials told us that due to the lack of funds, the center has not been able to follow replacement schedules for purchasing equipment or to prepare a comprehensive plan for the acquisition of high-cost equipment. To date, the center has not had the funds to replace an X-ray machine, which was used to study the effects of radiation on animal and cell cultures. Its machine, which officials said became unreliable and nonrepairable 5 years ago, would cost about $108,000 to replace, the center estimated.

In addition, center officials told us that certain regulatory activities have been delayed due to inadequate equipment. They said that the lack of equipment caused a 5-year delay in the center's establishment of guidance for approval of diagnostic ultrasound medical devices. The center has also delayed regulatory action on certain medical devices, such as pacemakers and silicone used in breast implants. Officials stated, for example, that without adequate equipment, they cannot perform work to determine the chemical features and toxicity of silicone.

The center also told us its equipment maintenance budget is insufficient. The center's maintenance budget for fiscal year 1989 is about $123,000, but center officials estimate that it should be increased to about $203,000.

FDA reports that it has asked for about $14 million to be included in its fiscal year 1990 budget to strengthen the agency's capability to evaluate the safety and effectiveness of biotechnological applications in food production and drug development. Of this $14 million, $1 million would be used by the Center for Foods to procure equipment. No specific estimates of the amount to be used by the Centers for Drugs or Devices for equipment were available.

Conclusions, Recommendations, and Industry Views

FDA is experiencing significant resource problems that may affect its ability to fulfill its legislative mandates. Before the Congress can act on FDA's problems, an accurate assessment of resource needs based on a prioritization of agency activities is needed. The agency has experienced increased responsibilities while its staffing levels have been reduced. FDA's high vacancy rate further compounds FDA's staffing problems. Inadequate office and laboratory space and scientific equipment add to FDA's problems in meeting its mission.

To resolve these problems, FDA estimates that it needs authorized funding for at least 2,000 additional positions. It also says it needs approximately $500 million to consolidate its facilities at one location, as well as additional funding to upgrade its laboratory equipment. It appears more staffing and resources are needed to carry out all currently assigned responsibilities. However, FDA needs a more comprehensive and credible basis for substantiating its estimates of resource requirements. In light of the continued increased demands on FDA, the agency should revisit many of the recommendations identified in the 1984 task force report.

Recommendations to the Congress

To provide a more accurate basis for determining FDA's resource needs, we recommend that the Congress require the Commissioner of FDA to make an agencywide assessment to identify and prioritize its activities and responsibilities. Specifically, FDA should:

- assess the agency's responsibilities and the staffing requirements to meet these responsibilities (based on present and future projections).
- determine the activities FDA can effectively undertake given a specified level of staffing increases (e.g., a 2-percent, 10-percent, or 15-percent increase over 1989).
- identify the management changes FDA would implement to match specified staffing levels with higher priority responsibilities (e.g., consolidation, shifting of low-priority tasks to third parties).

In order to effectively carry out the above recommendations, we further recommend that FDA determine the agencywide management information systems[1] it will need to assure that officials have the data to accurately assess (1) FDA's staff and resource needs and (2) how well its mission is being carried out and how effectively current resources are

[1]GAO's report ADP Planning: FDA's Plans to Improve Processing of Medical Device and Drug Applications (GAO/IMTEC-89-58, June 1989) provides guidance on the tasks necessary to plan, design, develop, and implement an automated management information system.

being used. Due to the urgency of FDA's problems, we believe that FDA should place a high priority on completing its comprehensive assessment.

We also recommend that FDA use the information it developed as a basis to assess its facility and equipment needs. This assessment would be intended to assure that space, laboratory, and equipment plans are synchronized with the agency's concentration of staffing resources on higher priority activities. Furthermore, FDA should prepare a timetable for the staffing, systems, and management changes it will implement as a result of its assessment.

Industry Views on FDA's Resource Needs

At the request of congressional staff, we obtained the views of the food, drug, and medical device industries on FDA's staffing, and other resource needs. These groups generally supported the need for additional support for FDA. Regarding staff, several of the associations expressed concern over turnover and noted that FDA needs additional funding to attract or retain personnel with sufficient expertise. They believe that problems with agency staffing contribute to lengthy delays in product reviews and may result in technical errors. According to some industry representatives, FDA also needs more funding to modernize its research equipment.

However, the industry associations cautioned that while FDA needs additional resources, the agency also needs to institute efficiencies in how it conducts its work and uses resources. Several of the representatives noted that FDA should (1) reexamine its mission, (2) establish work priorities, (3) consider other alternatives for obtaining additional resources and performing the agency's work, (4) establish a better system to track products in the review process to determine when delays may be occurring, and (5) hold reviewers more accountable for completing timely reviews.

Additions to FDA's Legislative Responsibilities (Fiscal Years 1980 to 1989)

FDA is responsible for carrying out the provisions of the Federal Food, Drug, and Cosmetic Act of 1938. This act has been amended many times. In addition, FDA's authority has been increased by other laws, including many enacted since 1980 that have added significantly to the demands placed on FDA. While most of these have primarily affected FDA, many have affected other federal agencies as well. For example, the Regulatory Flexibility Act (P.L. 96-354, 94 Stat. 1164 (1980)) requires that all agencies achieve greater participation by individuals and smaller institutions when regulations are being promulgated by the agencies that will affect them. Although not directed specifically at FDA, this act significantly increased FDA's burdens. Listed below are the major legislative provisions that increased FDA's responsibilities and a brief summary of the purpose of each statute.

Infant Formula Act of 1980

This act (P.L. 96-359, 94 Stat. 1190) established standards for the quality and safety of infant formulas. As amended by section 4014 of the Alcohol and Drug Abuse Amendments of 1986 (P.L. 99-570, Title IV, Subtitle A, 100 Stat. 3207-116), it requires that manufacturers of infant formula products test extensively for purity and the presence of required nutrients. In addition, manufacturers must retain records regarding their production of infant formula products. FDA is charged with establishing appropriate regulations to implement the act and with its monitoring.

Orphan Drug Act

This act (P.L. 97-414, 96 Stat. 2049 (1983)) has been amended frequently (for example, by the Health Promotion and Disease Prevention Amendments of 1984 (P.L. 98-551, 98 Stat. 2815); the Orphan Drug Amendments of 1985 (P.L. 99-91, 99 Stat. 387); and the Orphan Drug Amendments of 1988 (P.L. 100-290, 102 Stat. 90).

As amended, this act provides for the development of orphan drugs, defined as drugs for diseases and conditions that affect fewer than 200,000 persons nationally. It is intended to reduce costs and provide incentives for orphan drug development in several ways: (1) by providing tax credits for clinical testing on humans, (2) by providing exclusive marketing rights to orphan drug sponsors, (3) by establishing a board to coordinate federal agencies involved in drug research and regulation, and (4) by providing grants for the development of orphan products, including drugs, medical devices, and foods. Under this act FDA issued procedures outlining information drug manufacturers need to submit for designation and approval of their products as orphan drugs.

Federal Anti-Tampering Act	This act (P.L. 98-127, 97 Stat. 831 (1983)) makes it a federal crime to tamper with certain consumer products. FDA is authorized to investigate violations involving the possible tampering of products that it regulates.
Medicare and Medicaid Budget Reconciliation Amendments of 1984	Section 2304(c) (P.L. 98-369, Title III, 98 Stat. 1068) requires FDA to maintain a registry of all cardiac pacemaker devices and pacemaker leads for which payment is made under Medicare.
Drug Price Competition and Patent Term Restoration Act of 1984	Title I (P.L. 98-417, 98 Stat. 1585) establishes an approval procedure for generic versions of drugs previously approved as prescription drugs. It requires drug patent owners to submit information to FDA regarding patents on approved drugs. Generic copies of these patented drugs may be approved consistent with the appropriate patent laws.
Food Security Act of 1985	Subtitle F of title XVII (P.L. 99-198, 99 Stat. 1645) revises the standards governing the humane treatment of research animals. It requires researchers, including those at FDA, to (1) minimize animals' pain and discomfort by, among other things, providing veterinary care; (2) consult with a veterinarian in planning painful procedures to minimize pain; (3) allow animals recovery time between experiments; and (4) file a report if any deviations from the above rules are anticipated.
National Childhood Vaccine Injury Act of 1986	This act (Title III of an Act of Oct. 18, 1986, P.L. 99-660, 100 Stat. 3743), which was amended by the Vaccine Compensation Amendments of 1987 (P.L. 100-203, Title IV, Subtitle D, 101 Stat. 1330-221), establishes a no-fault compensation program making awards to those injured by certain childhood vaccines and mandates the reporting of childhood vaccine injuries. It requires manufacturers to maintain records on the production, testing, and handling of their vaccines and to report problems encountered. It also provides added FDA authority to recall hazardous vaccines and requires FDA, among others, to perform studies on childhood vaccines and the sufficiency of warnings and labels. Further, the act establishes a program to coordinate federal research, testing, licensing, production, and distribution of vaccines.

Drug Export Amendments Act of 1986

This act (P.L. 99-660, Title I, 100 Stat. 3743) permits the export of new domestically manufactured drugs or biologicals that are not yet approved for use in the United States but are approved for use in countries to which products are exported. FDA performs surveillance activities to ensure that exporting companies comply with requirements of this act.

Prescription Drug Marketing Act of 1987

This act (P.L. 100-293, 102 Stat. 95 (1988)) prohibits the reimportation of prescription drugs that have been found to be in violation of the Federal Food, Drug, and Cosmetic Act. It also bans the sale of drug samples and the resale of prescription drugs purchased by health care entities for their own use. The act provides a range of criminal and civil penalties for violations of these provisions.

Pesticide Monitoring Improvements Act of 1988

This act (P.L. 100-418, Title IV, Subtitle G, 102 Stat. 1411) requires FDA to establish a computerized data management system to record, summarize, and evaluate information on the use of pesticides on imported foods. On the basis of this information, FDA must make an annual report to the Congress. The act also requires establishing and maintaining cooperative agreements with major countries that are the sources of food imports into the United States in order to gather more specific data on U.S. pesticide tolerance requirements. It requires that, with respect to cooperative data collecting agreements with these countries, FDA coordinate its activities with certain other federal agencies and with appropriate international organizations.

The act also mandates that FDA supply state agencies with information on the use of pesticides when requested by those agencies. Furthermore, FDA is expected to obtain information on those responsible for pesticide monitoring and regulation in food exporting countries, the laboratories used by them to monitor the pesticides, and related government pesticide manuals or regulations in those countries. FDA must also participate in developing a long-range plan for improving methods of detecting pesticide use or residue.

Health Omnibus Programs Extension of 1988

This act (P.L. 100-607, 102 Stat. 3048) includes the AIDS Amendments of 1988 (Title II, 102 Stat. 3062). Among other things, it encourages the filing of exemption applications with HHS for investigative drugs that appear to be effective in the prevention and treatment of AIDS, but which have not yet been approved by FDA.

Generic Animal Drug and Patent Term Restoration Act

This act (P.L. 100-670, 102 Stat. 3971 (1988)) parallels similar legislation respecting generic drugs for humans by expediting the approval for generic animal drugs. If the drug will be given to food producing animals, additional testing is required to assure food safety. The act requires FDA to publish patent information on drugs that may legally be copied. It specifies when FDA may release safety and effectiveness data on a drug under approval and gives FDA the authority to require a veterinarian's order to dispense certain animal drugs.

Anti-Drug Abuse Act of 1988

Subtitle E of title II (P.L. 100-690, 102 Stat. 4230), among other things, criminalizes the distribution of anabolic steroids or human growth hormones except under FDA approval. Title X (102 Stat. 4539) of the act also requires FDA to inspect methadone clinics.

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