Memorandum

Date JUL 19 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Public Health Service's Identification of Program Management Control Areas for Federal Managers' Financial Integrity Act Evaluation (A-15-93-00013)

To
Philip R. Lee, M.D.
Assistant Secretary for Health

Attached is a final audit report on the Public Health Service's (PHS) process for identifying management control areas for the purpose of conducting management control evaluations required by the Federal Managers' Financial Integrity Act of 1982 (FMFIA). We found that PHS' policies and procedures do not assure that all programs and missions are identified for management control reviews required by FMFIA. As a result, audits have disclosed many programs not subjected to the management oversight intended by this law. An improved process should provide reasonable assurance that all major management control weaknesses have been detected and corrected through effective FMFIA compliance.

The report contains recommendations that focus on bringing PHS into full compliance with FMFIA by requiring agency management control officers to identify and document all PHS programs and related objectives, missions and legislation so that they will be subject to FMFIA evaluation. We are also recommending that the management control plan be routinely updated to reflect changes in program responsibilities.

We would appreciate receiving a status report within 60 days of the date of this report on your progress in implementing our recommendations. Should you wish to discuss this report, please call me, or your staff may contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PUBLIC HEALTH SERVICE'S IDENTIFICATION OF PROGRAM MANAGEMENT CONTROL AREAS FOR FEDERAL MANAGERS' FINANCIAL INTEGRITY ACT EVALUATION

JULY 1993 A-15-93-00013

Memorandum

Date JUL 19 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Public Health Service's Identification of Program Management Control Areas for Federal Managers' Financial Integrity Act Evaluation (A-15-93-00013)

To

Philip R. Lee, M.D.
Assistant Secretary for Health

This final audit report provides you with the results of our review of the Public Health Service's (PHS) compliance with the requirement of the Federal Managers' Financial Integrity Act of 1982 (FMFIA) that all its programs and missions be identified and segmented into management control areas that are subject to evaluation. Our review showed that the PHS process for identifying management control areas does not assure comprehensive and complete coverage of its programs and missions. The FMFIA evaluations form the basis for the agency head's annual reports to the President and Congress on the adequacy of agency management controls to guard against fraud, waste, and abuse, and assure that programs are effectively and efficiently carried out in accordance with applicable laws and agency missions and goals.

An initial step required by FMFIA is to identify an agency's operations and activities and segment them into management control areas. The areas are then scheduled for management control evaluations. The areas should be sufficiently customized to provide an accurate reflection of all requirements specified in mission statements and laws governing each PHS agency, including the Office of the Assistant Secretary for Health (OASH). The areas are to be included in a management control plan (MCP), which is a 5-year schedule for performing evaluations.

We found that PHS' policies and procedures do not contain sufficient guidance to assure that management control areas focus on programs, and that development of these areas is documented as required by Federal documentation standards.[1]

---

[1] Title 2--Policy and Procedures Manual for Guidance of Federal Agencies, Appendix II, Page 129, May 18, 1988, United States General Accounting Office.

Our analysis showed that PHS had taken the initiative to add many areas but most program areas in the MCP were added after auditors raised concerns about lack of coverage. This piecemeal approach has contributed toward audit findings of material management control weaknesses in program areas not covered by PHS' MCP. In addition, PHS does not have procedures for assuring compliance with laws not tied specifically to its programs and is susceptible to overlooking implementation of such legislation.

We are recommending that you require agency management control officers to identify and document all PHS programs and related objectives, missions and legislation so that they will be subject to FMFIA evaluation. We are also recommending that the MCP be routinely updated to reflect changes in program responsibilities.

BACKGROUND

The Office of Management and Budget (OMB) Circular A-123, which implements the FMFIA requirement for evaluating internal[2] control systems, specifies that:

> "Agencies shall establish and maintain a cost effective system of internal controls to provide reasonable assurance that Government resources are protected against fraud, waste, mismanagement or misappropriation and that both existing and new programs and administrative activities are effectively and efficiently managed to achieve the goals of the agency." (Underscoring supplied.)

Goals of the agency referred to by OMB are those general plans to achieve an agency's mission or missions. The mission of the agency is the overall purpose for which it exists. Missions should encompass requirements of laws, legislative history and related responsibilities specified in the agency's budget. Programs are activities related to missions. Personnel administration and accounting services, and other generic administrative or financial functions, support program activities.

The OMB Circular A-123 and the Department of Health and Human Services (HHS) Internal Control Manual establish steps for evaluating an agency's management controls. The five key

---

[2] The terms "internal controls" and "management controls" are synonymous.

steps are: 1) identifying an agency's operations and activities and segmenting them into management control areas; 2) conducting risk assessments; 3) performing management control reviews; 4) reporting on the adequacy of the agency's management controls; and 5) following up to assure that identified management control problems were corrected. Management control areas and schedules for evaluating them are to be included in the agency's 5-year MCP.

The HHS' Internal Control Manual requires operating divisions and staff divisions to assure that their program, administrative and financial activities are identified and appropriately segmented. The HHS defines segmentation as dividing the agency into management control areas (also known as assessable units) which should be sufficiently customized to focus on programs and missions of an agency. The HHS has noted several acceptable segmentation methods, all of which require that programs and missions be identified as a basis for developing management control areas for the MCP.

The PHS issued Internal Control Review Directive Number 1, Identification of Internal Control Areas/Event Control Points (Directive), in 1985, to provide guidance for identifying management control areas. In a 1992 update of this Directive on segmentation procedures, PHS noted that agency management control area managers are responsible for ensuring the accuracy of management control area descriptions and other information listed in MCP that involve their agencies. These managers also may recommend adding or deleting areas from the MCP inventory.

The PHS has designated the Director of the Office of Management, within OASH, as the PHS-wide management control officer. The Chief of OASH's Management Control Branch is the PHS-wide management control coordinator. These two officials are responsible for developing PHS' FMFIA policies and procedures, and for oversight of PHS' compliance with FMFIA. Each PHS agency also has a management control officer and a management control coordinator. These agencies and the amount budgeted in Fiscal Year (FY) 1992 are shown in the following table.

Public Health Service Agencies
Fiscal Year 1992 Budgets

Agency	Budget (millions)
Agency for Health Care Policy and Research (AHCPR)	$ 120
Agency for Toxic Substances and Disease Registry (ATSDR)	57
Centers for Disease Control and Prevention (CDC)	1,489
Food and Drug Administration (FDA)	752
Health Resources and Services Administration (HRSA)	2,409
Indian Health Service (IHS)	1,816
National Institutes of Health (NIH)	8,935
Substance Abuse and Mental Health Services Administration (SAMHSA)	3,092
Office of the Assistant Secretary for Health (OASH)	61
TOTAL	$18,731

OBJECTIVE, SCOPE AND METHODOLOGY

The objective of this review was to determine whether PHS has adequate policies and procedures to identify all its programs and missions for FMFIA evaluation. We reviewed the FMFIA and related legislative history, OMB Circular A-123, and the HHS and PHS internal control manuals. We analyzed policies, procedures, and processes used by PHS and its agencies for identifying management control areas.

We evaluated PHS' MCPs prepared from FYs 1989 to 1992, and reviewed audit reports issued by the Office of Inspector General (OIG) and the General Accounting Office (GAO) on PHS operations. We discussed processes used to identify areas for PHS' MCP with management control officials within OASH and at all eight PHS agency headquarters offices--AHCPR, CDC/ATSDR, FDA, HRSA, IHS, NIH, and SAMHSA. These offices are located in Bethesda, and Rockville, Maryland; and in Atlanta, Georgia. We also discussed compliance with laws with officials of PHS' Office of General Counsel (OGC). Our review was conducted between July and November 1992.

Our review was conducted in accordance with Government Auditing Standards except that we did not obtain agency comments. The agency, originally provided 30 days from the February 5, 1993 draft report date to submit comments, was provided subsequent extensions, but none were submitted. Thus, the views of the agency are not included in this report.

FINDINGS AND RECOMMENDATIONS

The PHS has developed procedures on how to make segmentation reviews and has tasked agency management control coordinators with ensuring the accuracy of management control area descriptions. While these managers may recommend adding and deleting areas from the MCP inventory, the PHS procedures do not provide guidance on identifying areas not already in the MCP or for assuring compliance with Federal documentation standards on linking the areas with programs and missions.

Our analysis showed that program management control areas in the MCP have evolved primarily from audit findings rather than from a process that systematically identifies programs and missions for FMFIA coverage. This piecemeal approach has contributed toward audit findings of material management control weaknesses in program areas not covered by PHS' MCP. Also, generic areas in the MCP are not linked to PHS programs, thus making it difficult to determine whether program objectives in these areas were being met. In addition, PHS does not have procedures for assuring compliance with laws that do not involve specific programs and, thus, is susceptible to overlooking implementation of such legislation.

Policies, Procedures and Processes

The Management Control Branch within OASH annually develops lists of management control areas and distributes them to the PHS agencies for review. The PHS Directive on segmentation tasks agency management control coordinators with providing information to this Branch on whether their agencies have responsibilities in these areas. While these managers may recommend adding and deleting areas from the MCP inventory, the PHS procedures do not provide guidance on identifying areas not already in the MCP or for assuring compliance with Federal documentation standards on linking the areas with programs and missions. It was not until recent years, after audits disclosed major program responsibilities not covered in PHS' MCP, that some agencies have become actively involved in identifying new areas.

We contacted PHS agency management control officials in each PHS agency and found that they had viewed their role as that of implementing the MCP developed by the OASH Management Control Branch. These officials stated that they traditionally have had little or no input in identifying management control areas. Most viewed the identification of new areas as an OASH Management Control Branch responsibility. The Chief of this branch recognized that management of FMFIA

is centralized. He expressed his belief that maintaining control at the highest level provides the best assurance of compliance with FMFIA. He also told us that PHS had used documents such as mission statements in developing management control area lists but could not provide documentation to support this assertion.

The CDC/ATSDR, FDA, IHS and NIH management control officials only recently began asserting a more substantial role in identifying new areas for the MCP. This view evolved after audits noted that program areas were not adequately covered. The IHS, the first PHS agency to provide us with an extensive plan for implementing the MCP, focused its plan on management control areas already in the PHS' MCP and areas where audits and management evaluations had identified management control deficiencies. Neither the IHS plan nor information provided by any of the other PHS agencies, however, provided substantiation that all programs and missions had been identified and properly reflected in management control areas.

Our review showed that PHS has not established a link between MCP generic areas and PHS' program areas and missions. It also showed that PHS' Directive on segmentation does not require establishment of such a link. The identification of all programs and missions and establishment of management control areas that focus on them is the cornerstone for development and evaluation of an agency's management controls. Management control standards required by FMFIA legislation, specify that documentation of management controls be purposeful and useful to managers in controlling their operations, and to auditors and others involved in analyzing operations.

Analysis of Program Coverage

We analyzed PHS' program and mission coverage by evaluating management control areas added to the MCP; issued audit reports disclosing material management control weaknesses in areas not previously covered in the MCP; and statements by management control officials in each agency and with PHS' management control officer.

Areas Added to MCP

Our evaluation of the basis for program management control areas added to the MCP for PHS showed that PHS had taken the initiative to add many areas but most of the additions could be linked to audit findings and initiatives indicating insufficient or no FMFIA coverage of the areas subsequently

added. In our FMFIA report for FY 1989,[3] other reports such as those listed in footnote[4] and discussions with agency officials, we noted deficiencies in program coverage in FDA and IHS. The following table shows the comparative increase in the number of program management control areas between FY 1989 and FY 1992 for all PHS agencies, including those of FDA and IHS. Of the 101 program areas subsequently added to the 18 program areas in the MCP for FY 1989, 91 were in these 2 agencies.

Comparative Summary of the Number of Program Management Control Areas in PHS' Management Control Plan for Fiscal Years 1989 and 1992

Agency-Specific	FY 1992	FY 1989
FDA	92	7
IHS	7	1
CDC and ATSDR	3[1]	-3
OASH	1	0
AHCPR	0	-[2]
HRSA	0	0
NIH	0	0
SAMHSA	0	0
PHS-Wide or applies to more than one agency[3] (See Appendix, p. 3 & 4)	16	7
Totals	119[4]	18[4]

Notes:

1 As is noted on page 9, the CDC/ATSDR subsequently proposed the addition of many areas as the result of our inquiries.

2 AHCPR did not exist as a separate agency in FY 1989.

3 PHS refers to these as functional areas.

4 For a detailed listing of the programmatic management control areas in PHS' MCP for FY 1992 and FY 1989, see Appendix.

---

3 Implementation of the Federal Managers' Financial Integrity Act for Fiscal Year 1989, A-12-89-00139, January 3, 1990.

4 Vulnerabilities in the Food and Drug Administration's Generic Drug Approval Process, A-15-89-00051, August 17, 1989; Need to Assure that Internal Controls Over Health Care Delivery Programs of the Indian Health Service are Adequately Evaluated, A-15-89-00068, April 16, 1990; Audit of Community Mental Health Centers Construction Grant Program - Phase I, A-05-91-00050, October 2, 1991; MAJOR NIH COMPUTER SYSTEM: Poor Management Resulted in Unmet Scientists' Needs and Wasted Millions, GAO/IMTEC-92-5, November 4, 1991; and Superfund Financial Activities of the Agency for Toxic Substances and Disease Registry for Fiscal Year 1990, A-15-91-00002, July 6, 1992.

The PHS provided us with a new MCP on November 24, 1992. This new plan includes substantially more program areas than those identified in the FY 1992 MCP. We have not performed a detailed review of the new plan.

Audits Disclosing Material Weaknesses

Our analysis of OIG and GAO audit reports showed the following examples of areas that should have been identified for FMFIA evaluation before the audits disclosed material weaknesses in the corresponding PHS programs. The examples are descriptions of PHS reported material weaknesses in a PHS agency program or mission support activity for which PHS had not identified management control areas for FMFIA evaluation. The examples are:

- inadequate management controls in FDA's generic drug process which resulted in drug companies misrepresenting information in requests for approvals for generic drugs, and in several employees giving preferential treatment to some drug companies in exchange for kickbacks.[5] This disclosure resulted in convictions of FDA employees and employees of pharmaceutical companies who were found to have participated in these illegal acts.

- a lack of Alcohol, Drug Abuse and Mental Health Administration, predecessor of SAMHSA, administrative controls over the monitoring of construction grants provided to community mental health centers.[6] Effective FMFIA reviews would have detected this problem before it culminated into an OIG recommendation that the agency recover $6.8 million from grantees who were consistently out of compliance with grant requirements, and the possibility that far more costs could have been incurred by Federal health insurance programs and the public as the result of ineffective enforcement in this program area. The OIG initiated this audit at the request of the Assistant Secretary for Health to follow up on our audit in 1984 which disclosed similar problems.

- inefficiencies found in use of computer resources at the NIH center that provides services to users for a fee.[7]

---

5 Vulnerabilities in the Food and Drug Administration's Generic Drug Approval Process, A-15-89-00051, August 17, 1989.

6 Audit of Community Mental Health Centers Construction Grant Program - Phase I, A-05-91-00050, October 2, 1991.

7 MAJOR NIH COMPUTER SYSTEM: Poor Management Resulted in Unmet Scientists' Needs and Wasted Millions, GAO/IMTEC-92-5, November 4, 1991.

The inefficiencies in this program could have been identified much earlier through FMFIA evaluations. A result might have been to find customers to use the excess resources, thus creating revenues to expand or fund other program activities.

Discussions With Management Control Officials

As was noted in the section of this report on "Policies, Procedures and Processes;" PHS agency management control officials traditionally have had little or no role in identifying management control areas, and that CDC/ATSDR, FDA, IHS and NIH management control officials only recently had begun asserting a more substantial role in identifying new areas for the MCP. We also noted in the section on "Areas Added to MCP," that a substantial number of program areas had been added for FDA and IHS after audits disclosed deficiencies in FMFIA coverage for these agencies.

We recently discussed with the CDC/ATSDR Associate Director for Management and Operations our concerns about insufficient FMFIA coverage of programs and missions in both agencies. Except for the program areas of health hazard evaluations at worksites, health training verification, and toxicological profiles; the MCP for CDC/ATSDR addressed only generic areas such as personnel and grants. In a September 10, 1992 memorandum to the Director of the OASH Office of Management, the CDC/ATSDR Associate Director for Management and Operations noted that they had reexamined their portion of the PHS' MCP, authorities and mission statements. This reexamination identified 30 program areas and 54 subareas of which only 7 of the program areas along with 18 subareas had previously been included in the PHS' MCP. As of December 1992, the PHS management control officer was assessing the need for inclusion of the newly identified CDC/ATSDR areas in the PHS' MCP.

The NIH Associate Director for Administration told us he did not think that NIH had sufficiently reviewed its mission statements to identify all of its program responsibilities and that he had reservations about the completeness of the MCP relative to NIH operations. In response to concerns we have raised, NIH's Associate Director for Administration, told us that NIH has retained a contractor to conduct a study of its management control program which includes segmentation of their programs and missions to comply with FMFIA.

At a departmentwide Management Oversight Council meeting, held in November 1992 to discuss approaches to address program coverage under FMFIA, the PHS management control officer outlined PHS' approach and suggested principles for program coverage. He advocated use of crosscutting program management

control areas wherever possible, and establishment of areas for specific programs with specialized or unique operations not covered by the crosscutting areas. He recognized that the MCP does not specifically identify all PHS programs and missions. He noted that:

- programs and missions should be linked to the MCP in ways that assure all programs and missions are identified for evaluation.

- in view of recent MCP expansions, the PHS has asked each agency to review the adequacy of their plans in light of principles recently drafted to better define program coverage.

Legislation Not Tied Specifically to Programs

Our review also disclosed that PHS does not have procedures for assuring compliance with legislation that is not program or mission specific, but that must be complied with in administering its programs. We have noted instances in recent years where PHS has not implemented this type of legislation. For example:

- the PHS began to implement the Program Fraud Civil Remedies Act of 1986 after we brought the matter to their attention in September 1990.[8]

- the IHS reported during FY 1991 that it had overlooked implementation of a Federal criminal law (18 U.S.C. 437) which generally forbids contracting or trading with Indians by Federal employees.

- after we disclosed that PHS had not planned or performed any FMFIA reviews focusing on assuring that accounting systems for the funds subject to the requirement of the Chief Financial Officers Act of 1990, the MCP for PHS began to reflect review requirements for these funds. The HHS, prior to the enactment of this law, published a plan in 1988 for audited financial statements for these funds.

The PHS management control coordinator told us that implementation of legislation is generally viewed as an event in any management control area where legislation plays a key role. In addition, the PHS' OGC was not aware of any mechanism for assuring that legislation is implemented unless

---

[8] OIG Memorandum to the Deputy Assistant Secretary for Health Operations on Implementation of Program Fraud Civil Remedies Act, A-15-90-00055, September 10, 1990.

it is tied specifically to PHS programs or operations. An official in the PHS' OGC told us that it is the responsibility of operations personnel to implement legislation. For these reasons, PHS is susceptible to overlooking implementation of laws and requirements not tied to specific programs or operations unless its FMFIA procedures adequately include requirements for evaluating their implementation.

CONCLUSIONS

The PHS' policies, procedures and processes for identifying management control areas are deficient in that they do not implement the HHS requirement that management control areas be sufficiently customized to focus on all programs for accomplishing the agency's missions. The PHS Directive does not provide detailed guidance on "how to" document and segment agency programs. Also, PHS does not have procedures for identifying and assuring implementation of legislation that is not program or mission specific, but which must be complied with in administering its programs. It is, therefore, susceptible to overlooking compliance with such legislation.

We believe that the lack of PHS procedures for establishing management control areas linked, through documentation, to programs and missions was a major cause of the following deficiencies revealed by our analysis:

- most program areas in the MCP were added after auditors raised concerns about lack of coverage.
- auditors have disclosed material weaknesses in program and mission support activities that had not been identified for PHS FMFIA evaluation at the time the weaknesses were discovered.
- management control officials at CDC/ATSDR and NIH recently began to take their own initiatives to segment the missions and programs of their agencies for FMFIA evaluations.

The CDC/ATSDR, FDA, IHS and NIH have responded to past audit findings by initiating efforts to identify all management control areas for the PHS' MCP. These actions underscore the need for PHS to revise its existing guidance to require all of its agencies to review mission statements and laws governing their agencies and programs, and assure that all of their programs and missions are documented and properly reflected in the MCP for PHS. Management control areas should be designed to assure effective coverage of all programs and missions by PHS agency, whether the programs are identified in individual management control areas or are linked to crosscutting areas.

We believe that management should develop a complete and comprehensive MCP that provides reasonable assurance that management control problems are detected and corrected before audits disclose that they are material weaknesses. This will require following a process, which has not yet been fully established in PHS. In this regard, PHS has recently told us that it has asked each of its agencies to review their plans in light of principles recently drafted to better define program coverage. However, until this effort is completed along with the evaluations of the adequacy of the management controls, OIG does not believe PHS can provide reasonable assurance as to the adequacy of PHS' management controls.

RECOMMENDATIONS

To bring PHS into full compliance with the FMFIA's requirement that its MCP provide an accurate reflection of operations and activities of each PHS agency, we recommend that you require the PHS management control officer to:

1. revise PHS guidance for identifying management control areas to require the management control officers of the various agencies to identify agency programs and missions and assure that they are properly segmented into management control areas.

2. require a documented link between all agency programs and missions and management control areas identified for FMFIA evaluation.

3. include all agency management control areas in PHS' MCP so that controls related to all programs and missions will be subject to the kind of evaluations required by FMFIA.

4. require that the MCP be routinely updated to reflect changes in responsibilities, missions, and laws relative to programs and missions of PHS agencies.

5. in consultation with OGC, develop procedures that focus on ensuring that legislation impacting PHS programs and missions, but not tied specifically to them, are implemented.

APPENDIX

PUBLIC HEALTH SERVICE
PROGRAMMATIC MANAGEMENT CONTROL AREAS

The left column of the following comparative list shows programmatic areas in the FY 1992 MCP and the right column indicates with an "X" those that were in the MCP for FY 1989. The list shows that majority of the areas added since FY 1989 were in FDA and IHS. These two agencies have received major audit attention during recent years. The following list was prepared prior to our receipt in November 1992, of an updated PHS' MCP which includes substantially more program areas than those identified in the FY 1992 MCP.

AREAS IDENTIFIED THROUGH FY 1992	AREAS IDENTIFIED THROUGH FY 1989
Food and Drug Administration	
1. 510(k) Tracking System	
2. Adverse Drug Reaction Reporting	
3. Adverse Reaction	
4. Animal Drug Research Program	
5. Bacterial and Allergenic Product	
6. Biochemical Toxicology	
7. Bioeffects Analysis, Tests and Measurement	
8. Biological Evaluation and Research	X
9. Biometry	
10. Biopharmaceutics	
11. Bioresearch Monitoring	
12. Blood and Blood Products	
13. Blood Bank Registration	
14. Chemical Contaminants Program	
15. Chemistry	
16. Color Certification	
17. Colors and Cosmetics Technology	X
18. Comparative Toxicology	
19. Compliance Activities	
20. Conformance Assessments of Voluntary Standards	
21. Consumer Affairs Program	
22. Control Testing and Release	
23. Devices and Radiological Health	X
24. Diet-Toxicity Interactions	
25. Drug Product Recall Activities	
26. Drug Evaluation and Research	
27. Drug Registration and Listing Activities	
28. Education and Assistance	
29. Elemental Analysis Research Program	
30. Emergency and Epidemiology Operations	
31. Enforcement Action Program-Headquarters	
32. Enforcement Regulation Program-Headquarters	
33. Enforcement Policy Program-Field	
34. Enforcement Action Program-Field	
35. Establishment Inspection	

	AREAS IDENTIFIED THROUGH FY 1992	AREAS IDENTIFIED THROUGH FY 1989
36.	Field Laboratory Program	X
37.	Field Investigational Program	
38.	Food Composition, Standards, Labeling and Economics	X
39.	Food Safety and Applied Nutrition	
40.	Food and Color Additives Petition Review and Policy Development	
41.	Food-Borne Biological Hazard	
42.	Foreign Inspection Program	
43.	Generic Drug Evaluation	
44.	Genetic Toxicology	
45.	Good Manufacturing Practices	
46.	Import Operation Program	X
47.	Infant Formula Notifications	
48.	Investigational Support Program	
49.	Investigational Device Exemption	
50.	Laboratory Support Program Headquarters	
51.	Less-Than-Effective Drugs	
52.	Medical Product Quality Assurance Program	
53.	Microbiology	
54.	Molecular Biology and Natural Toxins	
55.	Natural Toxin Research Program	
56.	New Drug Applications	
57.	Office of the Commissioner	
58.	Orphan Products Grant Program	
59.	Over the Counter Drug Program	
60.	Patent Term Restoration Program	
61.	Pesticides and Industrials	
62.	Pesticides and Chemical Contaminants	
63.	Policies, Procedures and Guidelines	
64.	Post Approval and Monitoring of Animal Drugs and Feed and Devices	
65.	Post Market Surveillance	
66.	Pre-Amendments Premarket Approval Application	
67.	Preapproval Evaluation of Animal Drugs and Food Additives	
68.	Premarket Approval	
69.	Premarket Notification 510(k)	
70.	Prescription Drug Advertising and Labeling	
71.	Product Licensing Application Review	
72.	Project on Caloric Restriction	
73.	Radiological Health Standards Enforcement	
74.	Reclassification	
75.	Registration and Licensing	
76.	Regulatory Affairs	
77.	Reproductive and Developmental Toxicology	
78.	Research Services	
79.	Research and Policy Development	
80.	Seafood Product Research Program	
81.	Security of Data and Documents-FDA	
82.	State Contracts Programs Headquarters	
83.	State Program-Field	

	AREAS IDENTIFIED THROUGH FY 1992	AREAS IDENTIFIED THROUGH FY 1989
84.	Statutory Timeframe-FDA	
85.	Surveillance and Epidemiology	
86.	Technical Assistance	
87.	Technical Support to Small Manufacturers	
88.	Total Diet Research Program	
89.	Toxicological Research	
90.	Veterinary Medical Research	
91.	Veterinary Medicine	X
92.	Viral Products	
	Indian Health Service	
93.	Admittance and Reimbursement Procedures-Eligibility	X
94.	Alcoholism and Substance Abuse Activities	
95.	Contract Health Services	
96.	Health Promotion and Disease Prevention	
97.	Medicare/Medicaid Program	
98.	Sanitation Facility Construction	
99.	Urban Indian Health Program	
	Centers for Disease Control/Agency for Toxic Substances and Disease Registry	
100.	Health Hazard Evaluations at Worksites	X
101.	Health Training Verification	X
102.	Toxicological Profiles	X
	Office of the Assistant Secretary for Health	
103.	Sanitation Facilities Construction	
	PHS-Wide - Applies to more than one agency[9]	
104.	Emergency Preparedness - Accounting for Expenses (PHS-wide)	
105.	Emergency Preparedness - Obtaining Reimbursements (PHS-wide)	
106.	Evaluation Funds (SAMHSA, CDC, HRSA, NIH and OASH)	X
107.	Fines and Charges for Services (PHS-wide)	X
108.	Gift Administration (PHS-wide)	X
109.	Grants (PHS-wide)	X
110.	Hospital Accreditation (IHS, NIH and HRSA Hospitals and Clinics)	
111.	Intramural Research - Acquisition and Evaluation of Scientific Data (SAMHSA, CDC, FDA, HRSA, and IHS)	
112.	Intramural Research - Animal Care	

[9] PHS refers to these as functional areas.

AREAS IDENTIFIED THROUGH FY 1992	AREAS IDENTIFIED THROUGH FY 1989
(SAMHSA, CDC, FDA, HRSA, NIH, and AHCPR) . .	X
113. Intramural Research - Program Management and Scientific Misconduct (SAMHSA, CDC, FDA, HRSA, and IHS)	
114. Intramural Research - Programs and Projects (SAMHSA, CDC, FDA, HRSA, and IHS)	
115. Intramural Research - Review and Dissemination of Research Products (SAMHSA, CDC, FDA, HRSA, and IHS)	
116. Medical Waste (IHS, SAMHSA, CDC, FDA, HRSA, NIH, and OASH)	
117. Patents, Copyrights, and Royalties (PHS-wide)	X
118. Program Fraud Civil Remedies Act (PHS-wide)	
119. Program Users Fees (PHS-wide)	X