

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**OIG OVERSIGHT OF FDA ACTIVITIES:
A SUMMARY REPORT**



**Richard P. Kusserow
INSPECTOR GENERAL**

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OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program, and management problems, and recommends courses to correct them.

OFFICE OF AUDIT SERVICES

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

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The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil money penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

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The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in these inspection reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

This report was prepared under the direction of Emilie Baebel, Chief, Public Health and Human Services Branch. Participating in this project were the following people:

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Department of Health and Human Services

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OEI-12-92-00200

EXECUTIVE SUMMARY

PURPOSE

This summary report provides information on the oversight activities of the Office of Inspector General (OIG) in connection with the Food and Drug Administration (FDA). It discusses five major management challenges facing FDA which have been identified through OIG audits, investigations, and inspections, and OIG recommendations for improvement.

BACKGROUND

The FDA is responsible for regulating a wide array of products, including most of the nation's food supply, human and veterinary drugs, cosmetics, medical devices, and blood banks. Through product approval activities, FDA ensures that drugs and devices are safe and effective for their intended uses before they are marketed to the nation's consumers. Through surveillance and monitoring activities, FDA ensures that standards are met in the day-to-day processing, manufacturing, and handling of products it regulates.

The Office of Inspector General (OIG) is charged with preventing and detecting fraud, waste, and abuse, and promoting effectiveness and efficiency in the Department's programs, including FDA. The OIG conducts and supervises audits, investigations, and evaluations related to the Department's programs, identifies systematic weaknesses giving rise to opportunities for fraud and abuse, and makes recommendations to strengthen management systems and to promote effectiveness and efficiency.

ISSUES

Over the past several years OIG audits, investigations, and evaluations in FDA have identified several common problems which FDA management must address. These include the need to

- ▶ restore integrity to FDA's product approval process;
- ▶ vigorously detect and investigate potential fraud and abuse;
- ▶ invigorate FDA's inspections of manufacturing and processing facilities;
- ▶ ensure that FDA can respond to individuals and businesses out of compliance with the Food, Drug, and Cosmetic Act; and
- ▶ create and use reliable data management systems.

These problems are widely recognized. In addition to the OIG's discussion of these problems, the Advisory Committee on the Food and Drug Administration (the Edwards Commission) discussed them at some length in its final report, and the Commissioner of Food and Drugs has discussed the challenge of addressing these issues in public statements and testimony before the Congress.

CONCLUSIONS

The issues and conclusions in this report summarize those presented in greater detail in previously released OIG reports. The issues here highlight the major areas requiring attention. The conclusions summarize more detailed recommendations in the individual reports. The OIG is monitoring FDA's efforts to implement the recommendations found in the original reports. In general, we believe FDA must act to

- ▶ improve its product approval systems to ensure equitable and fair treatment of applicants, including the development of "first-in, first-out" policies, and standard operating procedures and guidelines for reviewers;
- ▶ obtain necessary enforcement authorities, such as embargo authority, subpoena authority, and civil monetary penalty authority, and use those authorities to encourage compliance with the Food, Drug, and Cosmetic Act and punish violators;
- ▶ conduct appropriate systems analysis to ensure that useful information systems are in place to provide FDA management with necessary information to track workload and workflow, and to ensure that information being obtained from regulated industries meets FDA monitoring needs for timely, accurate information;
- ▶ identify resource needs, delegating authorities to the States where appropriate, and relying on user fees to supplement budget authority and augment resources, where necessary; and
- ▶ develop a full-scale criminal investigative capability with trained, experienced investigators.

We believe that these steps are essential if FDA is to meet its numerous statutory responsibilities and meet the challenges of the coming decade.

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INTRODUCTION

PURPOSE

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To accomplish its mission, FDA has a budget of almost \$700 million (Fiscal Year 1991). Over 5,000 staff are distributed among the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Veterinary Medicine in FDA headquarters. A field force composed of almost 2,500 persons organized in 6 regions and 21 district offices inspects and monitors facilities such as food warehouses, blood banks, and drug and device manufacturers.

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- ▶ restore integrity to FDA's product approval process,
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- ▶ create and use reliable data management systems.

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The issues and conclusions in this report summarize those presented in greater detail in previously released OIG reports. The findings here highlight the major areas requiring attention. The recommendations summarize more detailed recommendations in the individual reports. The OIG is monitoring FDA's efforts to implement the recommendations found in the original reports.

ISSUES

THE FDA NEEDS TO RESTORE INTEGRITY TO ITS PRODUCT APPROVAL PROCESS.

The Edwards Commission noted in its final report that "the generic drug scandal exposed the agency's vulnerability to fraudulent data [and] improper inducements."¹ Our work in investigating the generic drug scandal, as well as audits we have conducted documenting inadequate internal controls in the drug approval process and the medical device 510(k) process, lead us to conclude that ensuring integrity in product approval is of the utmost importance and warrants continued scrutiny.

Generic Drug Scandal

Over the past 3 years, the generic drug industry has been rocked by a series of prosecutions resulting from OIG investigations. The prosecutions have occurred in two phases: a corruption phase, which involved generic drug companies giving illegal gratuities to FDA employees, and a fraud and false statements phase, in which the companies engaged in various deceptions regarding testing and manufacturing their products.

Prosecutions are completed on corruption charges resulting from these investigations. Over a 2-year period, three generic drug companies, five company officials, one industry consultant, and five FDA employees were convicted and sentenced in this phase, in which companies paid to receive favorable processing of their generic equivalents.

In the second round of prosecutions on charges of fraud, false statements, and manufacturing malpractice, two companies have been sentenced for obstructing an FDA investigation into irregularities in the bioequivalency testing required for generic drug approval. A major generic drug company was fined \$10 million, plus \$380,000 to defer the cost of the OIG and FDA investigations, for substituting a brand name product for the company's generic product in testing for bioequivalency. The laboratory which conducted the tests was fined \$200,000 for its part in the deception, which included replacing the brand name product with the generic when FDA investigators arrived on the scene. One company official was sentenced to 2 years and 2 months in jail for making these statements to FDA. An additional 13 company representatives and 2 laboratory representatives have been charged.

After these revelations, the OIG embarked on a joint effort with the FDA to provide bribery awareness training to its employees. We hope that this training will help

¹Advisory Committee on the Food and Drug Administration, U.S. Department of Health and Human Services, "Final Report of the Advisory Committee on the Food and Drug Administration," May 1991, p. 25.

restore integrity to all the approval processes performed by the FDA by heightening FDA employee sensitivity to the financial impact of their day-to-day decisions and regulatory activities.

Lack of Internal Controls in Product Approval

An OIG audit of FDA's generic drug approval process identified systemic weaknesses in conducting and managing reviews which allowed fraud and abuse to occur, including the lack of guidelines and standard operating procedures to ensure the consistent review of applications, and the lack of a "first-in, first-out" review policy.² The lack of consistency and standard operating procedures in reviewing Abbreviated New Drug Applications (ANDAs) was also a primary concern expressed by generic drug manufacturers in a series of interviews we conducted in 1990 to assess the perspectives of industry on FDA's generic drug approval process.³

Problems of this kind continue to plague the Office of Generic Drugs. Recently, the OIG has documented serious problems with FDA's review of drug master files (DMFs) in approving ANDAs. These drug master files provide important information on the facilities, processes, or articles used in manufacturing, processing, packaging, and storing drugs or drug ingredients. Our audit documented that no policies or procedures are in place at FDA to require review of DMFs. As a result, some FDA chemists always review DMFs which are referenced in an ANDA; others rely on previous reviews of DMFs conducted by other chemists in connection with a prior ANDA; and still others do neither. Without such DMF reviews, FDA cannot ensure that generic drug ingredients are safe and effective.⁴

The lack of internal controls to ensure that product applications are reviewed and approved in accordance with accepted policies and procedures is an FDA-wide problem. Some of these same weaknesses were also identified in our audit of FDA's 510(k) process, through which device manufacturers notify FDA of their intent to market a medical device. In this audit, we documented FDA's lack of procedures to sequence reviews and document decisions to ensure timely, fair, and complete 510(k) evaluations. We also found that FDA lacks a comprehensive quality control system to

²Office of Inspector General, "Vulnerabilities in the Food and Drug Administration's Generic Drug Approval Process," A-15-89-00051, August 1989.

³Office of Inspector General, "Perspectives of Drug Manufacturers: Abbreviated New Drug Applications," OEI-12-90-00770, February 1990; Office of Inspector General, "Perspectives of Drug Manufacturers: Investigational New Drug and New Drug Applications," OEI-12-09-0771, February 1990.

⁴Office of Inspector General, "Evaluation of Drug Master File Reviews by the Food and Drug Administration," A-15-90-00004, July 1991.

evaluate and critique the adequacy of manufacturer submissions, or a management information system that tracks reviewer workload and productivity.⁵

In recognition of the common vulnerabilities in all of FDA's product approval activities, internal control weaknesses were characterized as a FDA-wide problem in the Department's 1990 Federal Manager's Financial Integrity Act report. We are now conducting an audit to determine what actions FDA has taken to rectify problems we identified in the ANDA review process and plan future follow-ups in other product review areas.

To correct these deficiencies, FDA must establish a system of strict accountability in which procedures and policies are in place regarding product approval and management ensures staff adherence to those policies and procedures. One way FDA management can accomplish this is through the use of data systems which track activities and results, a subject discussed in more detail later in this report.

THE FDA NEEDS TO VIGOROUSLY DETECT AND INVESTIGATE POTENTIAL FRAUD AND ABUSE.

The generic drug scandal brought to light the importance of strengthening fraud and abuse detection among regulated industry and FDA employees. The OIG continues to have reservations about FDA's ability to conduct criminal investigations due to a lack of trained, experienced investigators. We are also concerned about the lack of close coordination between FDA and the U.S. Attorney's office when criminal activity is first alleged.

Review of the FDA Denver District Office

The Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, has expressed concern regarding some generic drug investigations which were conducted by FDA, involving possible fraudulent statements provided during the ANDA approval process. At the Subcommittee's request, we conducted a review to assess the FDA Denver District Office's ability to detect and investigate possible fraud in the ANDA approval process. We determined that inspectors in the FDA's Denver District Office failed to identify fraud during the course of one of the generic drug company inspections because they lacked the requisite experience and training. As a result, they failed to request and review the pertinent documents from which fraud was eventually disclosed.

⁵Office of Inspector General, "Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Process," A-15-89-00065, July 1990.

Review of the FDA Orlando District Office

The Subcommittee on Oversight and Investigations also asked the OIG to examine the activities of the Orlando District Office and comment on that office's activities to detect, investigate, and prosecute illegal drug diversion. From a review of the allegations received and investigations undertaken by the Orlando District Office, we are concerned about the resources and investigative methods employed to address Prescription Drug Marketing Act violations in South Florida. The Orlando District Office does not have the resources to devote the time necessary to address this persistent type of criminal activity. In addition, normal FDA inspection processes have not proven successful in detecting and investigating these crimes. Trained criminal investigators employing traditional law enforcement methods rather than FDA inspection activities are necessary to adequately pursue these crimes.

Coordination with the U.S. Attorney's Office

Another significant problem which we have identified in reviewing and assessing FDA criminal investigations is that the investigative process is insulated from the prosecutorial process. It is our position that when criminal activities are initially alleged, FDA should consult immediately with the U.S. Attorney's office. FDA should then proceed with its criminal investigation under the direction of the U.S. Attorney's office, in order that any prosecution warranted by the facts will be successful.

THE FDA NEEDS TO INVIGORATE ITS INSPECTIONS OF MANUFACTURING AND PROCESSING FACILITIES.

Another significant outcome of our ongoing work in investigating the generic drug scandal was to document the importance of FDA surveillance and inspection activity. A generic drug firm official we interviewed in 1990 put it bluntly: "[FDA staff] do not go to laboratories or plants as part of their review. They underutilize their field staff, one of their best assets." Yet FDA field offices are virtually inundated with mandates and responsibilities, and their priorities are often to deal with the latest crisis at the expense of routine monitoring. The Edwards Commission summed up the problem well: "Too often, staffing limitations shape FDA's inspection decisions." In several reports, we have documented the effects of this resource squeeze and suggested various ways of addressing it. In October of 1990, FDA instituted new policies regarding the use of field inspection staff as part of the ANDA approval process. Inspection records are verified and a plant inspection is conducted if one has not been performed within the past 2 years prior to approving the application by FDA.

Inspections of Medical Device Firms

In a recent study, we found that FDA is not meeting its biennial good manufacturing practices (GMP) inspection requirement for medical device firms. An internal FDA review found that, between 1981 and 1987, half of all firms FDA inspected for compliance with GMP requirements were not reinspected within 24 months. We also

documented that as of August 1988, 19 percent of all active class II and III device manufacturers had never been inspected. According to district office officials, understaffing, combined with the need to respond to various public health crises on foods, blood banks, as well as drugs and devices, leaves FDA unable to meet all of its regulatory responsibilities.⁶

Inspections of Low-Risk Food Firms

Although FDA believes that the potential exists for serious problems with low-risk food firms, it assigns a low priority to these inspections. In 1989, FDA planned to conduct over 14,000 food safety inspections; it conducted only 54 percent of them because of other priorities and lack of resources. In addition, not all food firms are known to FDA or state inspectors; these firms may never be inspected.

In a recent report, the OIG has recommended completely reorienting the way FDA conducts food inspections. We believe that FDA should delegate low-risk food inspection authority to the States and concentrate its efforts on standard setting and other monitoring activities. We have recommended that FDA (1) design a uniform system that ensures both a systematic identification of all food firms and inspection results; (2) develop requirements for low-risk food safety inspections and certify which States meet these requirements; (3) allow certified States to conduct inspections of low-risk firms (conducting its own inspections only in those States which are not certified); (4) seek legislation to provide inspectors with the enforcement tools necessary to do their job effectively; and (5) collect an inspection user fee from all food firms to fund low-risk food safety inspections of both FDA and the States that meet FDA's certification requirements. In this kind of system, FDA can target its scarce inspection resources to drug and device facilities, and concentrate its food safety work on monitoring States' activities and providing technical assistance and coordination.⁷

FDA has indicated its support of the general principles we espoused. A subsequent survey of 10 States revealed that considerable support exists in the States for such a system. The key to cooperation from the States is that the user fees collected by FDA be used to support their activities.

⁶Office of Inspector General, "FDA Medical Device Regulation: From Premarket Review to Recall," OEI-09-90-00040, February 1991.

⁷Office of Inspector General, "FDA Food Safety Inspection," OEI-05-90-01070, August 1991.

User Fees

User fees may be one answer to FDA's resource squeeze. We believe that user fees, properly structured, could help alleviate staffing and resource difficulties in other areas of FDA. User fee systems supporting application review and approval and inspections in other Federal regulatory agencies (including the Nuclear Regulatory Commission, the Federal Communications Commission, the Environmental Protection Agency, and the Federal Energy Regulatory Commission), have met with some success.

The OIG has assessed the applicability of user fee systems to FDA. We concluded that FDA user fees represent a legitimate method of recovering regulatory costs. Although there are many ways of structuring a user fee system at FDA--a hybrid system of annual registration charges and processing fees for applications and inspections might be most workable--imposition of such fees would be consistent with principles upheld in other Federal agencies: that regulation provides benefits to the regulated, and that those who benefit from the agency's activities ought to be required to pay for them.⁸

THE FDA MUST BE ABLE TO RESPOND TO INDIVIDUALS AND BUSINESSES OUT OF COMPLIANCE WITH THE ACT.

Once violators are identified, FDA must have the necessary authority to take appropriate action. Our 1990 work on medical devices, referenced earlier, provided information to the Congress that was useful in developing the Safe Medical Device Act of 1990. Until this act was passed, FDA lacked authority to impose civil money penalties on medical device firms. Furthermore, as our work in food safety has documented, the agency lacks the power to embargo products such as suspected adulterated foodstuffs, even though all States have such powers. Thus, FDA depends on States to effect an embargo to prevent potentially hazardous foods from being marketed.

Businesses are also beginning to test the boundaries of the Federal Food, Drug, and Cosmetic Act. One area in which this appears to be especially true is drug promotion. Some drug manufacturers are advertising their products prior to FDA approval, in clear violation of the law; some are promoting their products to physicians and hospitals in a way that might violate the Medicare and Medicaid anti-kickback statute; many are testing FDA's commitment and vigilance in regulating their promotional activities by calling their activities "exchanges of scientific information."

The OIG has categorized four types of payments and gifts to physicians used by manufacturers to promote prescription drugs: payments for physicians involved in studies, payments for speaking engagements, payments for attending educational and

⁸Office of Inspector General, "Implementing User Fees at the Food and Drug Administration: A Case Study," OEI-12-90-02020, July 1990.

promotional programs, and unsolicited gifts. Some of these practices are pure promotion disguised as legitimate business arrangements. We believe that these types of practices deserve continued attention by FDA and the OIG.⁹

Some manufacturers are promoting drugs before they are approved by FDA. Recent work by our office revealed that one drug company was improperly claiming that an experimental animal drug is safe and effective, prior to its approval by FDA.¹⁰ To combat these types of practices, FDA has established a hotline for whistleblowers and is augmenting staff in the division of drug advertising and labeling to oversee drug promotion.

THE FDA MUST CREATE AND USE RELIABLE DATA MANAGEMENT SYSTEMS.

The need for FDA to establish a system of strict accountability, in which management oversight plays a key role, was briefly mentioned earlier in this report. Using data systems which track activities and results can help achieve this goal.

Generic Drug Management Information System

Our findings in auditing the generic drug approval process, in which managers were not monitoring assignments and the progress of chemists in conducting their reviews, demonstrates the vulnerabilities which result from poor, nonexistent, or unused management information systems. Our report documents that the management information system in the generic drug division does not produce reports FDA needs to effectively monitor day-to-day operations or to detect indications of possible manipulation of the generic drug review and approval process. The management information system also does not provide specific information for efficiently and effectively using current staff resources or adequately forecasting future staff resource needs.¹¹ The FDA is attempting to use the management information system to project resource needs but to date has not corrected the other noted vulnerabilities.

⁹Office of Inspector General, "Promotion of Prescription Drugs through Payments and Gifts," OEI-01-90-00480, August 1991.

¹⁰Office of Inspector General, "Need for the Food and Drug Administration to Review Possible Improper Pre-approval Promotional Activities," A-15-91-00007, May 1991.

¹¹Office of Inspector General, "Review of the Food and Drug Administration's Generic Drug Management Information System," A-15-89-00063, July 1990.

The Edwards Commission confirmed our findings, concluding that "information relating to performance, workload activity trends, and resource allocations is uneven and not consistently available."¹² This situation must be corrected.

FDA'S Drug Registration and Listing System

In addition to creating information systems which provide managers with important information on internal matters, it is essential that FDA have in place data systems which provide managers with accurate intelligence about regulated industry. As discussed earlier, our work in food safety revealed that some unknown number of food firms are never subject to inspection because FDA does not know they exist. A recent report just released by our office documents problems with another data system, the drug registration and listing system (DRLS) maintained by the agency. As a catalog of all commercially distributed drugs, the DRLS is used for a variety of purposes: it has been used in the generic drug investigations to identify questionable products, for example, and in support of Operation Desert Storm, it was used by the Defense Department to identify antidotes for poison gas.

We found that the DRLS is not complete or accurate: 8,000 products were on the market but missing from the file, and approximately 1,400 products were in the file but off the market. This inaccuracy was due to deficiencies at FDA as well as a failure of drug companies to supply the needed information as required by regulation. FDA is now rectifying some of these problems by redesigning procedures, converting to a new computer system, and considering penalties for manufacturers who do not provide accurate data.¹³

The Commissioner of Food and Drugs responded to concerns about the adequacy of FDA's data management systems in testimony before the Senate Committee on Government affairs, saying, "Supporting FDA's mission with state-of-art information systems is essential to support the complex process of decisionmaking throughout the agency." FDA has taken action in some areas to introduce new data systems--such as the initiative in the imported foods area to link FDA systems with those maintained by the U.S. Customs Service--but much more is left to accomplish in this area. As an indication of this need, the Edwards Commission recommended immediately reviewing information system needs and systems upgrading.

¹²Advisory Committee on the Food and Drug Administration, U.S. Department of Health and Human Services, "Final Report of the Advisory Committee on the Food and Drug Administration," May 1991, p. 33.

¹³Office of Inspector General, "The FDA's Prescription Drug File," (draft), OEI-03-90-02300, July 1991.

CONCLUSIONS

In connection with its many audits, inspections, and investigations of FDA, the OIG has made numerous specific recommendations for correcting identified problems. The OIG is monitoring FDA's efforts to implement the recommendations found in the original reports. In general, we believe that FDA must act to

- ▶ improve its product approval systems to ensure equitable and fair treatment of applicants, including the development of "first-in, first-out" policies, and standard operating procedures and guidelines for reviewers;
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APPENDIX A

OIG REPORTS CONCERNING FDA

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

"Perspectives of Drug Manufacturers: Abbreviated New Drug Applications," OEI-12-90-00770, February 1990; Office of Inspector General, "Perspectives of Drug Manufacturers: Investigational New Drug and New Drug Applications," OEI-12-09-0771, February 1990.

"Evaluation of Drug Master File Reviews by the Food and Drug Administration," A-15-90-00004, July 1991.

"Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Process," A-15-89-00065, July 1990.

"FDA Medical Device Regulation: From Premarket Review to Recall," OEI-09-90-00040, February 1991.

"FDA Food Safety Inspection," OEI-05-90-01070, August 1991.

"Implementing User Fees at the Food and Drug Administration: A Case Study," OEI-12-90-02020, July 1990.

"Promotion of Prescription Drugs through Payments and Gifts," OEI-01-90-00480, August 1991.

"Need for the Food and Drug Administration to Review Possible Improper Pre-approval Promotional Activities," A-15-91-00007, May 1991.

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