Memorandum

Date SEP 25 1995

From Deputy Inspector General
for Audit Services

Subject Report on the Audit of the Food and Drug Administration's Prescription Drug User Fee Account for Fiscal Year 1994 (A-17-95-00046)

To Robert J. Byrd
Associate Commissioner
for Management
Food and Drug Administration

The attached report presents the results of the Certified Public Accounting Firm, Gardiner, Kamya & Associates (GK&A), audit of the Food and Drug Administration's Prescription Drug User Fee Account (the PDUFA Account) financial statements for the Fiscal Year (FY) ended September 30, 1994. The Office of Inspector General (OIG) provided a Contracting Officer's Technical Representative during the audit to exercise technical oversight and, additionally, conducted a quality control review of GK&A's audit working papers.

In the attached auditor's opinion, the PDUFA Account's statements of financial position and the related statement of operation and changes in net position as of and for the year ended September 30, 1994 are presented fairly, in all material respects, in conformity with the basis of accounting described in the Summary of Significant Accounting Policies accompanying the financial statements. The independent auditor's report on the PDUFA Account's internal control structure and on its compliance with laws and regulations are also provided. No audit was performed for FY 1993.

As noted in the internal control section of GK&A's report, a reportable condition was noted in that the PDUFA Account does not have a formal internal control structure in place which addresses the unique control needs for the accumulation of costs allocated the PDUFA Account. They recommended that the PDUFA Account management develop a cost accumulation procedures manual which describes each procedure of the process of accumulating and allocating cost related to the PDUFA Account. The PDUFA Account management concurs with this recommendation.

During our oversight of the GK&A's work, we found nothing to indicate that GK&A's opinion on the PDUFA Account's FY 1994 financial statements was inappropriate or cannot be relied upon. Nor did we find anything to indicate that the auditor's reports on the internal control structure and on compliance with laws and regulations were inappropriate or cannot be relied upon.

We would appreciate being advised within 60 days on the status of corrective actions. Should you wish to discuss the issues raised by the review, please call me or have your staff contact Joseph E. Vengrin, Acting Assistant Inspector General for Accounting and Financial Management Audits, at (202) 619-1157. Please refer to the Common Identification Number A-17-95-00046 in all correspondence relating to this report.

Thomas D. Roslewicz

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REPORT ON THE AUDIT OF THE FOOD AND DRUG ADMINISTRATION'S PRESCRIPTION DRUG USER FEE ACCOUNT FOR FISCAL YEAR 1994

THOMAS D. ROSLEWICZ
Deputy Inspector General
for Audit Services

SEPTEMBER 1995
A-17-95-00046

Gardiner, Kamya & Associates, P.C.

Management Consultants and Certified Public Accountants
1717 K Street, N.W., Suite 601 Washington, D.C. 20036
Phone: 202 857-1777

To the Office of Inspector General
of the Department of Health and Human Services
and the Board of Governors of the Food and Drug Administration (FDA)

INDEPENDENT AUDITOR'S REPORT ON FINANCIAL STATEMENTS

We have audited the accompanying statement of financial position of the Food and Drug Administration's Prescription Drug User Fee Account (the PDUFA Account) as of September 30, 1994, and the related statement of operations and changes in net position for the year then ended. These financial statements are the responsibility of the PDUFA Account's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with generally accepted auditing standards; *Government Auditing Standards (1994 revision)*, issued by the Comptroller General of the United States; and the Office of Management and Budget (OMB) Bulletin 93-06, *Audit Requirements for Federal Financial Statements*. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

Because we were not engaged to audit the statements of cash flows and budget and actual expenses, we did not extend our auditing procedures to enable us to express an opinion on cash flows and compliance with budget restrictions for the year ended September 30, 1994. Accordingly, we express no opinion on them.

In accordance with *Government Auditing Standards,* we have also issued a report dated July 14, 1995 on our consideration of the PDUFA Account's internal control structure and a report dated July 14, 1995 on its compliance with laws and regulations.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the PDUFA Account at September 30, 1994, and the results of its operations for the year then ended in conformity with the basis of accounting described in Note 1.

Our audit was conducted for the purpose of forming an opinion on the financial statements referred to in the first paragraph of this report taken as a whole. The information presented in the management's Overview of the PDUFA Account is not a required part of the financial statements but is supplementary information required by OMB Bulletin No. 94-01, *Form and Content of Agency Financial Statements,* or the Prescription Drug User PDUFA Act of 1992.

Such information has not been subjected to the auditing procedures applied in the audit of the financial statements and, accordingly, we express no opinion on it.

This report is intended for the information of the PDUFA Account's management, the Department of Health and Human Services, Office of Inspector General, and the Office of Management and Budget. However, this report is a matter of public record and its distribution is not limited.

Gardiner, Kamya & Associates, P.C.

July 14, 1995

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To the Office of Inspector General
of the Department of Health and Human Services
and the Board of Governors of the Food and Drug Administration

INDEPENDENT AUDITOR'S REPORT ON INTERNAL CONTROL STRUCTURE

We have audited the statement of financial position and the statement of operations and changes in net position of the Food and Drug Administration's Prescription Drug User Fee Account (the PDUFA Account) as of September 30, 1994, and have issued our report thereon dated July 14, 1995.

We conducted our audit in accordance with generally accepted auditing standards, *Government Auditing Standards (1994 revision),* issued by the Comptroller General of the United States, and Office of Management and Budget Bulletin 93-06, *Audit Requirements for Federal Financial Statements.* Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

In planning and performing our audit of the financial statements of the PDUFA Account for the year ended September 30, 1994, we obtained an understanding of the internal control structure. With respect to the internal control structure, we obtained an understanding of the design of relevant policies and procedures and whether they have been placed in operation, and we assessed control risk in order to determine our auditing procedures for the purpose of expressing our opinion on the financial statements and not to provide assurance on the internal control structure. Accordingly, we do not express such an opinion. Our consideration included an understanding of the significant internal control structure policies and procedures and assessing the level of control risk relevant to all significant cycles, classes of transactions, or account balances.

The management of the PDUFA Account is responsible for establishing and maintaining an internal control structure. In fulfilling this responsibility, estimates and judgements by management are required to assess the expected benefits and related costs of internal control structure policies and procedures. The objectives of an internal control structure are to provide management with reasonable, but not absolute, assurance that assets are safeguarded against loss from unauthorized use or disposition and that transactions are executed in accordance with management's authorization and recorded properly to permit the preparation of reliable and timely financial reports in conformity with the basis of accounting described in *Note 1* of the financial statements. Because of inherent limitations in any internal control structure, errors or irregularities may nevertheless occur and not be detected. Also, projection of an evaluation of the structure to future periods is subject to the risk that procedures may become inadequate because of changes in conditions or that the effectiveness of the design and operation of policies and procedures may deteriorate.

For the purpose of this report, we have classified the significant internal control structure policies and procedures in the following categories: revenue and receipts; obligations, cost accumulation and cost allocation; and payroll.

For all the internal control structure categories listed above, we obtained an understanding of the design of relevant policies and procedures, determined whether they have been placed in operation, assessed control risk, and tested significant controls that were placed in operation.

We noted certain matters involving the internal control structure and its operation that we considered to be reportable conditions under standards established by the American Institute of Certified Public Accountants and OMB Bulletin 93-06. Reportable conditions involve matters coming to our attention relating to significant deficiencies in the design or operation of the internal control structure that, in our judgment, could adversely affect the entity's ability to record, process, summarize, and report financial data consistent with the assertions of management in the financial statements.

The identified reportable condition, as defined above, is summarized below with further explanation in Exhibit 1 of this report.

Reportable Condition

- **Cost accumulation methodologies and procedures** - The PDUFA Account does not have a formal internal control structure in place which addresses the unique control needs for the accumulation of costs allocated to the PDUFA Account.

  The cost allocated to the PDUFA Account is accumulated in four major components of the Food and Drug Administration: the Center for Drug Evaluation and Research (CDER), the Center for Biologic Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and the Office of Commissioner (OC). In each Component, the methodologies and procedures used are informal and the complexity and highly labor-intensive nature of these methodologies and procedures may result in material misstatement of the costs allocated to the PDUFA Account.

A material weakness is a condition in which the design or operation of one or more of the internal control structure elements does not reduce to a relatively low level the risk that errors or irregularities in amounts that would be material in relation to the financial statements being audited may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.

Our consideration of the internal control structure would not necessarily disclose all matters in the internal control structure that might be reportable conditions and, accordingly, would not necessarily disclose all reportable conditions that are also considered to be material weaknesses as defined above. We believe the reportable condition described above is not a material weakness.

However, we also noted other matters involving the internal control structure and its operation that we will report to the PDUFA Account's management in a separate letter.

In accordance with *Government Auditing Standards*, we have also issued an unqualified report

dated July 14, 1995 on our audit of the PDUFA Account's statement of financial position and the statement of operations and changes in net position and a report dated July 14, 1995 on its compliance with laws and regulations.

This report is intended for the information of the PDUFA Account's management, the Department of Health and Human Services, Office of Inspector General, and the Office of Management and Budget. However, this report is a matter of public record and its distribution is not limited.

Gardiner, Kamiya & Associates, P.C.

July 14, 1995

EXHIBIT 1

INDEPENDENT AUDITOR'S EXHIBIT ON REPORTABLE CONDITIONS

INTERNAL CONTROL STRUCTURE - COST ACCUMULATION AND ALLOCATION PROCEDURES

CONDITION

The PDUFA Account does not have a formal internal control structure in place which addresses the unique control needs for the accumulation of cost allocated to the PDUFA Account.

The methodologies and procedures used for accumulating costs for and allocating these costs to the PDUFA Account differ widely across the four components of FDA and sometimes within each component, the methodologies and procedures used differ from cost center to cost center. For example, in FY 1994, a basic workload measurement (BWM) survey which utilizes a combination of "retro-look" and "real-time study" was used to accumulate the costs of CBER allocated to the PDUFA Account. The "retro-look" approach is a BWM survey whereby supervisors in CBER were requested to estimate the percentage of effort expended by their group on certain pre-defined activities. The "real-time" study on the other hand is a BWM survey whereby employees in selected cost centers of CBER, for a specified time frame (i.e. one quarter), complete time sheets on a daily basis recording the actual time spent performing certain pre-defined activities. During the same FY 1994, the total cost of CDER allocated to the PDUFA Account was accumulated using a combination of the results of a 16-week real-time study conducted by Arthur Andersen and a direct method of accumulating costs.

In each division, the methodologies and procedures used are informal and the complexity and highly labor-intensive nature of these procedures may result in material misstatement of the costs allocated to the PDUFA Account.

CAUSE

The Prescription Drug User Act (PDUFA) was enacted in September, 1992. Fiscal year 1994 was the first year of full-scale operations under the Act and the management of the PDUFA Account may not have come to a realization of the need to establish formal procedures which address the unique characteristics of accounting needs under the Act.

CRITERIA

The Accounting and Audit Act of 1950 (31 U.S.C. 66a) as amended by the Federal Managers' Financial Integrity Act of 1982 requires that, in order to ensure compliance with subsection (a)(3), executive agencies should establish internal accounting and administrative controls in accordance with standards prescribed by the Comptroller General that provide reasonable, but not absolute, assurance that revenues and expenditures applicable to agency operations are properly recorded and accounted for to permit the preparation of accounts and reliable financial and statistical reports and to maintain accountability.

The Comptroller General Internal Control Standards requires that the internal control structure for federal agencies provide a management trail, also known as an audit trail,

to enable management to determine whether procedures followed by personnel are those authorized by management and consistently and accurately applied.

EFFECT

The absence of a formal cost accumulation and allocation procedures manual creates doubts about whether the methodologies and procedures that were used by staff to accumulate and allocate costs to the PDUFA Account were authorized or intended by management. Note, there was no formal review and approval of the process for accumulating and allocating FY 1994 costs related to the PDUFA Account.

In addition, the absence of a formal cost accumulation and allocation procedures manual may be responsible for:

(i) the use of methodologies and procedures that were authorized or intended by management;

(ii) inefficient and ineffective training of new employees;

(iii) difficulties monitoring the application of methodologies and procedures.

RECOMMENDATION

Due to the cumbersome nature of the process for accumulating the costs allocated to PDUFA Account and since the Act does not specify the accounting policies and procedures to be used, we recommend that the PDUFA Account develop a cost accumulation procedures manual which describes each procedure of the process of accumulating and allocating costs related to the PDUFA Account and delineates the responsibility for the review and approval of the cost accumulated and allocated to the PDUFA Account. Presently, each division that is involved in the process of the review of human drug has some description of the procedures used. In some instances those procedures are informal. These procedures need to be consolidated and approved by the Agency for use in the accumulation of costs related to the process for the review of human drug applications.

EXHIBIT 2

FOOD AND DRUG ADMINISTRATION (FDA) COMMENTS
on the
OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "FINANCIAL STATEMENT AUDIT OF FDA'S PRESCRIPTION DRUG USER FEE ACT ACCOUNT for FY 1994"

OIG RECOMMENDATION AND FDA COMMENTS

OIG RECOMMENDATION

We recommend that FDA develop a cost accumulation procedures manual which describes each procedure of the process for accumulating and allocating costs related to FDA's Prescription Drug User Fee Act (PDFUA) account and delineates the responsibility for the review and approval of the cost accumulated and allocated to the PDUFA account. The manual should consolidate existing cost accumulation and allocation procedures used by FDA's divisions involved with the process of review of human drug applications.

FDA COMMENTS

We concur with OIG's recommendation and plan to prepare a policies and procedures manual which will document the specific methodologies and processes used by FDA to capture all costs related to the process for review of human drug applications and how such costs are allocated to the PDUFA account.

Currently, each FDA component involved with the process for review of human drug applications has informal written procedures which describe its system for capturing and measuring program activity. In addition, FDA's Office of Financial Management has written procedures which describe the steps it takes to compile the costs (obligations) related to the process for review of human drug applications and how it calculates the amounts applicable to PDUFA. These procedures had been provided to the auditors during their fieldwork.

The FDA plans to consolidate the existing procedures into the recommended manual, which will also designate those officials who are responsible for reviewing and approving FDA components' and Office of Financial Management calculations.

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To the Office of Inspector General
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and the Board of Governors of the Food and Drug Administration

INDEPENDENT AUDITOR'S REPORT ON COMPLIANCE WITH LAWS AND REGULATIONS

We have audited the statement of financial position and the statement of operations and changes in net position of the Food and Drug Administration's Prescription Drug User Fee Account (the PDUFA Account) as of September 30, 1994, and have issued our report thereon dated July 14, 1995.

We conducted our audit in accordance with generally accepted auditing standards, *Government Auditing Standards*, issued by the Comptroller General of the United States, and Office of Management and Budget Bulletin 93-06, *Audit Requirements for Federal Financial Statements.* Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

Compliance with laws and regulations applicable to the PDUFA Account is the responsibility of the PDUFA Account's Management. As part of obtaining reasonable assurance about whether the financial statements are free of material misstatements, we performed tests of the PDUFA Account's compliance with certain provisions of the following laws and regulations that may directly affect the financial statements and certain other laws and regulations designed by OMB, the PDUFA Account, and the Office of Inspector General, including but not limited to the:

- Prescription Drug User PDUFA Act of 1992
- Budget and Accounting Procedures Act of 1950;
- Federal Managers' Financial Integrity Act of 1992 (FMFIA)
- Prompt Payment Act;
- Chief Financial Officers Act of 1990 (CFO);
- Debt Collection Act of 1982;
- Anti-deficiency Act;
- Civil Service Reform Act;
- Civil Service Retirement Act;
- Fair Labor Standards Act.
- Federal Employees Compensation Act
- Federal Employees Life Insurance Act

We also obtained an understanding of management's process for evaluating and reporting on internal control and accounting systems as required by the Federal Managers' Financial Integrity Act (FMFIA) and compared the FDA's most recent FMFIA reports with the evaluation we conducted of the PDUFA Account's internal control structure.

However, the objective of our audit was not to provide an opinion on overall compliance with such provisions. Accordingly, we do not express such an opinion.

The results of our tests indicate that, with respect to the items tested, the PDUFA Account complied, in all material respects, with the provisions referred to in the preceding paragraphs. With respect to items not tested, nothing came to our attention that caused us to believe that the PDUFA Account had not complied, in all material respects, with those provisions.

In accordance with *Government Auditing Standards,* we have also issued a report dated July 14, 1995 on our audit of the PDUFA Account's statement of financial position and the statement of operations and changes in net position which was unqualified and a report dated July 14, 1995 on our consideration of the PDUFA Account's internal control structure.

This report is intended for the information of the PDUFA Account's management, the Department of Health and Human Services, Office of Inspector General, and the Office of Management and Budget. However, this report is a matter of public record and its distribution is not limited.

Gardiner, Kamya & Associates, P.C.

July 14, 1995