

**Memorandum**

Date . SEP 25 1995
Deputy Inspector General
From for Audit Services
Subject Report on the Audit of the Food and Drug Administration's Revolving
Fund for Certification and Other Services for Fiscal Year 1994
(A-17-94-00040)
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, Kanya & Associates (GK&A), audit of the Food and Drug Administration's Revolving Fund for Certification and Other Services (the Certification Fund) 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 Certification Fund'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 Certification Fund's internal control structure and on its compliance with laws and regulations are also provided.

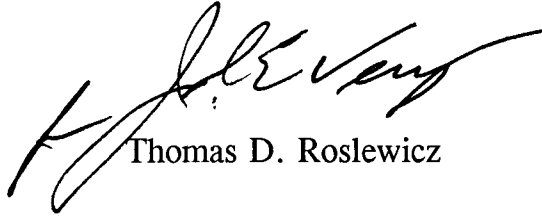
For FY 1993, the firm of Clifton, Gunderson & Co. (CG&C) was engaged to audit the Certification Fund's financial statements. The CG&C also expressed an unqualified opinion on these statements.

During our oversight of the GK&A's work, we found nothing to indicate that GK&A's opinion on the Certification Fund's FY 1994 financial statements was inappropriate or cannot be relied upon. Nor did we find

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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.

Should you wish to discuss this report, 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-17-94-00040 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
REVOLVING FUND FOR CERTIFICATION
AND OTHER SERVICES
FOR FISCAL YEAR 1994**



THOMAS D. ROSLEWICZ
Deputy Inspector General
for Audit Services

SEPTEMBER 1995
A-17-94-00040

Gardiner, Kamy & 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

INDEPENDENT AUDITOR'S REPORT ON FINANCIAL STATEMENTS

We have audited the accompanying statement of financial position of the Food and Drug Administration's Revolving Fund for Certification and Other Services (the Certification Fund) 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 Certification Fund's management. Our responsibility is to express an opinion on these financial statements based on our audit. The firm of Clifton, Gunderson & Co. was engaged to audit the financial statements of the Certification Fund for the year ended September 30, 1993. The Clifton, Gunderson & Co. report dated March 31, 1994, expressed an unqualified opinion on those financial statements.

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 (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 Certification Fund's internal control structure and a report dated July 14, 1995 on its compliance with laws and regulations.

In our opinion, the statement of financial position and the related statement of operations and changes in net position, present fairly, in all material respects, the financial position of the Food and Drug Administration's Revolving Fund for Certification and Other Services 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 Food and Drug Administration's Certification Fund 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*. 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 Certification Fund'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 & Associates, P.C.
July 14, 1995

Gardiner, Kamy & Associates, P.C.

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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 financial statements of the Food and Drug Administration's Revolving Fund for Certification and Other Services (the Certification Fund) as of and for the year ended 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 Food and Drug Administration's Certification Fund 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 Certification Fund 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, fixed assets, purchases and disbursements, 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.

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 under standards established by the American Institute of Certified Public Accountants. A material weakness is a reportable 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. We noted no matters involving the internal control structure and its operation that we consider to be material weaknesses as defined above.

However, we noted other matters involving the internal control structure and its operation that we will report to the Certification Fund'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 Certification Fund'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 Certification Fund'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.

Gardner, Kanya & Associates, P.C.
July 14, 1995

Gardiner, Kamy & Associates, P.C.

Management Consultants and Certified Public Accountants

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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 COMPLIANCE WITH LAWS AND REGULATIONS

We have audited the financial statements of the Food and Drug Administration's Revolving Fund for Certification and Other Services (the Certification Fund) as of and for the year ended 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 Certification Fund is the responsibility of the Certification Fund's Management. As part of obtaining reasonable assurance about whether the financial statements are free of material misstatements, we performed tests of the Certification Fund'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 Certification Fund, and the Office of Inspector General, including but not limited to the:

- Budget and Accounting Procedures Act of 1950;
- Prompt Payment Act;
- Chief Financial Officers Act of 1990;
- Federal Managers' Financial Integrity Act of 1992 (FMFIA);
- Debt Collection Act of 1982;
- Antideficiency 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 Certification Fund'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 Certification Fund 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 Certification Fund 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 Certification Fund'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 Certification Fund's internal control structure.

This report is intended for the information of the Certification Fund'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.

Hardison, Kanya & Associates, P. C.
July 14, 1995