2001 M Street, NW
Washington, DC 20036

Independent Auditors' Report on Consolidated Financial Statements

The Inspector General, U.S. Department of Health and Human Services and the Commissioner of the Food and Drug Administration:

We have audited the accompanying consolidated balance sheets of the Food and Drug Administration (FDA), an operating division of the U.S. Department of Health and Human Services (DHHS) as of September 30, 2002 and 2001, and the related consolidated statements of net cost, changes in net position, and financing, and the combined statement of budgetary resources for the years then ended (collectively referred to as "consolidated financial statements"). These consolidated financial statements are the responsibility of the FDA's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 01-02, *Audit Requirements for Federal Financial Statements*. Those standards and OMB Bulletin No. 01-02 require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the FDA, as of September 30, 2002 and 2001, and its net costs, changes in net position, budgetary resources, and reconciliation of net costs to budgetary obligations for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The information in the Management Discussion and Analysis, Required Supplementary Stewardship Information, and Required Supplementary Information sections is not a required part of the consolidated financial statements but is supplementary information required by accounting principles generally accepted in the United States of America or OMB Bulletin No. 01-09, *Form and Content of Agency Financial Statements*. We have applied certain limited procedures, which consisted principally of inquiries of management regarding the methods of measurement and presentation of this information. However, as part of our limited procedures applied to the Required Supplementary Information, we were unable to assess control risk relevant to FDA's intragovernmental transactions and balances with non-FDA trading partners, as required by OMB Bulletin 01-02. The FDA did not confirm intragovernmental transactions with most of its trading partners to enable the reconciliations of these transactions. Further, we did not audit this information and, accordingly, we express no opinion on it.

In accordance with *Government Auditing Standards*, we have also issued reports dated December 9, 2002, on our consideration of the FDA's internal control over financial reporting and its compliance with certain provisions of laws and regulations. Those reports are an integral part of an audit performed in accordance with *Government Auditing Standards*, and should be read in conjunction with this report in considering the results of our audit.

KPMG LLP

December 9, 2002

2001 M Street, NW
Washington, DC 20036

Independent Auditors' Report on Internal Control over Financial Reporting

The Inspector General, U.S. Department of Health and Human Services
and the Commissioner of the Food and Drug Administration:

We have audited the consolidated balance sheet of the Food and Drug Administration (FDA), an operating division of the U.S. Department of Health and Human Services (DHHS), as of September 30, 2002, and the related consolidated statements of net cost, changes in net position, and financing, and the combined statement of budgetary resources for the year then ended, (collectively referred to as the "consolidated financial statements"), and have issued our report thereon dated December 9, 2002. We conducted our audit in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 01-02, *Audit Requirements for Federal Financial Statements*.

In planning and performing our fiscal year 2002 audit, we considered the FDA's internal control over financial reporting by obtaining an understanding of the FDA's internal control, determining whether internal controls had been placed in operation, assessing control risk, and performing tests of controls in order to determine our auditing procedures for the purpose of expressing our opinion on the consolidated financial statements. We limited our internal control testing to those controls necessary to achieve the objectives described in OMB Bulletin No. 01-02 and *Government Auditing Standards*. We did not test all internal controls relevant to operating objectives as broadly defined by the Federal Managers' Financial Integrity Act of 1982. The objective of our audit was not to provide assurance on the FDA's internal control. Consequently, we do not provide an opinion on internal control over financial reporting.

Our consideration of internal control over financial reporting would not necessarily disclose all matters in the internal control over financial reporting that might be reportable conditions. Under standards issued by the American Institute of Certified Public Accountants, reportable conditions are matters coming to our attention relating to significant deficiencies in the design or operation of the internal control over financial reporting that, in our judgment, could adversely affect the FDA's ability to record, process, summarize, and report financial data consistent with the assertions by management in the consolidated financial statements. Material weaknesses are reportable conditions in which the design or operation of one or more of the internal control components does not reduce to a relatively low level the risk that misstatements, in amounts that would be material in relation to the consolidated 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. Because of inherent limitations in any internal control, misstatements due to error or fraud may occur and not be detected.

We noted a matter, described below, involving the internal control over financial reporting and its operation that we reported in our report last year and that we again consider to be a reportable condition.

Internal Controls Over Information Systems Should Be Enhanced

We reviewed the FDA's internal controls over information systems and noted the following:

Security Program. We assessed the FDA's security program and, although there was improvement in this area, we noted that the FDA has not prepared risk assessments for all major financial applications. We also noted improvements are needed in documenting and approving detailed incident response procedures and procedures should be developed to address compliance with security awareness training for delinquent users. Therefore, we recommend that the FDA's Office of Information Resource Management (OIRM) develop detailed guidance for the preparation of comprehensive risk assessments. With the guidance prepared, we recommend that the Office of Financial Management (OFM) conduct risk assessments and complete certification and accreditation statements for major financial applications. We further recommend that detailed incident response procedures be developed and approved by management. Last, we recommend that improvements be made to the FDA's security awareness training regarding delinquent users.

Access Controls. We assessed the FDA's management efforts related to financial systems and, although we noted continued improvement in this area, we believe that certain matters related to granting and monitoring of user access, adherence to the FDA-wide guidelines for remote access, database access configuration, local area network log settings, password assignment for servers, and restrictions surrounding network ports and services could be improved. Therefore, we recommend that OIRM improve the access control procedures, implement policies and procedures to reduce the potential for unauthorized access, and ensure adherence to the FDA standards.

Change Management. We assessed the FDA's management efforts related to financial systems to ensure that system integrity can be relied upon and, although we noted that controls have been established, improvements could be made. Detailed procedures should be included in the OFM's software development and change control policies and procedures, configuration management and change controls should be established on financial platforms, and management approval for production program changes should be improved. Therefore, we recommend that OFM and OIRM work together to develop, establish and implement detailed procedures, configuration management and change controls, and ensure production changes are approved by management.

Service Continuity. We assessed the FDA's business resumption efforts and noted that the Automated Information Systems Contingency Plan has not been completed in accordance with the FDA-wide policy. We further noted that financial system backup tapes should be rotated to an off-site location on a frequent basis. Last, the FDA needs to strengthen its disaster recovery planning activities and identify an alternate data processing facility. Therefore, we recommend OFM and OIRM make improvements to the FDA's disaster recovery plans, backup tape storage, disaster recovery planning, and recovering operations in the event of an unexpected business interruption.

Additional Required Procedures

As required by OMB Bulletin No. 01-02, we considered the FDA's internal control over Required Supplementary Stewardship Information by obtaining an understanding of the FDA's internal control, determining whether these internal controls had been placed in operation, assessing control risk, and performing tests of controls. Our procedures were not designed to provide assurance on internal control over Required Supplementary Stewardship Information, and, accordingly, we do not provide an opinion thereon.

As further required by OMB Bulletin No. 01-02, with respect to internal control related to performance measures determined by management to be key and reported in the Management's Discussion and Analysis section of the Annual Report, we obtained an understanding of the design of significant internal controls relating to the existence and completeness assertions. Our procedures were not designed to provide

assurance on internal control over reported performance measures, and, accordingly, we do not provide an opinion on such controls.

We also noted other matters involving internal control and its operation that we have reported to the management of the FDA in a separate letter dated December 9, 2002.

This report is intended solely for the information and use of the FDA's management, the DHHS Office of the Inspector General, OMB, and Congress and is not intended to be and should not be used by anyone other than these specified parties.

KPMG LLP

December 9, 2002

2001 M Street, NW
Washington, DC 20036

Independent Auditors' Report on Compliance with Laws and Regulations

The Inspector General, U.S. Department of Health and Human Services and the Commissioner of the Food and Drug Administration:

We have audited the consolidated balance sheet of the Food and Drug Administration (FDA), an operating division of the U.S. Department of Health and Human Services (DHHS), as of September 30, 2002, and the related consolidated statements of net cost, changes in net position, and financing, and the combined statement of budgetary resources for the year then ended (collectively referred to as the "consolidated financial statements"), and have issued our report thereon dated December 9, 2002. We conducted our audit in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 01-02, *Audit Requirements for Federal Financial Statements.*

The management of the FDA is responsible for complying with laws and regulations applicable to the FDA. As part of obtaining reasonable assurance about whether the FDA's consolidated financial statements are free of material misstatement, we performed tests of the FDA's compliance with certain provisions of laws and regulations, noncompliance with which could have a direct and material effect on the determination of the consolidated financial statement amounts, and certain provisions of other laws and regulations specified in OMB Bulletin No. 01-02, including certain requirements referred to in the Federal Financial Management Improvement Act (FFMIA) of 1996. We limited our tests of compliance to the provisions described in the preceding sentence, and we did not test compliance with all laws and regulations applicable to the FDA. However, providing an opinion on compliance with laws and regulations was not an objective of our audit, and, accordingly, we do not express such an opinion.

The results of our tests of compliance disclosed no instances of noncompliance with other laws and regulations discussed in the second paragraph of this report, exclusive of FFMIA, that are required to be reported under *Government Auditing Standards* or OMB Bulletin No. 01-02.

Under FFMIA, we are required to report whether the FDA's financial management systems substantially comply with (1) Federal financial management systems requirements, (2) applicable Federal accounting standards, and (3) the United States Government Standard General Ledger at the transaction level. To meet this requirement, we performed tests of compliance with FFMIA Section 803(a) requirements.

The results of our tests disclosed instances, described below, in which the FDA's financial management systems did not substantially comply with the Federal financial management systems requirements discussed in the preceding paragraph.

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Federal financial management systems requirements noncompliance. Our tests revealed that the FDA's accounts receivable, cost management, and property systems are not in compliance with the Federal financial management system requirements as follows:

- The accounts receivable system does not support the calculation, generation and posting of billings under interagency agreements based on the billing source, event and/or time period.
- The core financial system does not assign indirect costs to interim and final cost objects, or allow for multilevel assignments and reassignments of cost.
- The interface between the Asset Management System (AMS) and the general ledger is not electronic. Although an electronic interface is not required under the guidelines, this condition results in a reconciliation process between the AMS and the general ledger that is cumbersome and leads to reconciling items not being posted timely. It should be noted that an electronic interface has been implemented between the AMS and the general ledger in October 2002.

The results of our tests disclosed no instances in which FDA's financial management systems did not substantially comply with federal accounting standards and the United States Government Standard General Ledger at the transaction level.

This report is intended solely for the information and use of the FDA's management, the DHHS Office of Inspector General, OMB, and Congress and is not intended to be and should not be used by anyone other than these specified parties.

KPMG LLP

December 9, 2002