DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: June 17, 1994

From: Acting Director, Office of Device Evaluation
Center for Devices and Radiological Health

Subject: Office of Device Evaluation Annual Report for Fiscal Year 1993

To: Director
Center for Devices and Radiological Health

Attached is the ODE Annual Report for Fiscal Year 1993. This is the first full report that has issued since the FY 91 Annual Report. The Preface contains background information and provides an orientation that will be of interest to you.

On behalf of the ODE staff and management, I wish to thank all of the CDRH offices for providing ODE support and help during the past year. We look forward to a very productive FY 94.

Susan Alpert

Susan Alpert, Ph.D., M.D.

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1993

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

Acknowledgements

The PMA, IDE, and 510(k) staff offices, in conjunction with Eileen Marshall of the Office of Information Systems, provided most of the data used in the report. Many staff members within ODE Review Divisions and the Program Management Office also made significant contributions of data and information for the report. The report was edited by Betty Facchine, Publications Support Staff, Office of Management Services.

Carl T. DeMarco
Project Officer

Table of Contents

Preface

This Office of Device Evaluation (ODE) Annual Report, for Fiscal Year 1993, is the first comprehensive report that has been issued by ODE since the FY 91 Annual Report. This report, therefore, includes information of an archival nature from FY 92, to maintain continuity of information about the device evaluation program. As such, it should provide a baseline of data for future assessment of performance in the device evaluation program.

Since FY 91, ODE has experienced an intense period of programmatic and organizational change. The program has been the subject of extensive oversight audits and investigations by external agencies, including congressional committees, the Office of the Inspector General, and the General Accounting Office. ODE also has undergone internal reviews, such as that by the Committee on Clinical Review. As a result of these oversight activities and the Center's own "Management Action Plan" activities, a variety of management initiatives have been implemented yielding many new and significant programmatic changes. These changes include an emphasis on strong scientific reviews, enhanced clinical reviews, improved documentation of the administrative record, new expedited review procedures, a risk based approach to the intensity of submission reviews, and more thorough prefiling reviews.

There have also been tremendous changes in the ODE staff. New leadership has assumed responsibility for the device review program at both the office level and within the review divisions. There also has been an influx of new clinicians (medical officers) and scientific reviewers. All new staff members have had to undergo formal and on the job training.

As a result of these major changes, the medical device evaluation program, beginning in FY 91 and continuing through most of FY 93, experienced variations in output and efficiency.

A great deal of credit goes to the ODE staff for their perseverance during this period of transition. They have worked very hard and their efforts have resulted in the improvements we have seen in the early months of FY 94. I thank them and encourage them to keep up the good work! Appreciation is also expressed to Center management and the other CDRH Offices for their support and understanding during this period of transition.

Susan Alpert, Ph. D., M.D.
Acting Director, Office of Device Evaluation

EXECUTIVE SUMMARY
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
FISCAL YEAR 1993

The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health is responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research or marketing. The following are the highlights of the activities of ODE for Fiscal Year 1993 (FY 93). These highlights are explained more fully in the body of the report.

Workload

During FY 93 ODE received 16,869 total submissions. This represents a decrease of 1,217 from the all time high of 18,086 total submissions received in FY 92. The FY 93 total receipts represents the third largest number of total submissions ever received during one fiscal year.. The same is true for the number of major submissions: PMAs, PMA supplements, IDEs, IDE amendments, IDE supplements, and 510(k)s. We received a total of 10,952 major submissions during FY 93, a decrease of 398 from the record number of 11,350 major submissions received in FY 92.

On the output side, ODE reviewed 9,837 major submissions, which represents an increase of 588 from the 9,249 submissions reviewed in FY 92. This represents the reversal of a two year trend of a decreasing number of major submissions reviewed in FY 91 and FY 92.

Resources

Unlike previous years, there was no ceiling allocated within ODE for FTEs for FY 93. The actual FTE usage during this fiscal year was 273, an increase of 10 over the number of FTEs used in FY 92. ODE ended the year with 291 employees on board, an increase of 24 from the 276 employees on board at the end of last year.

In FY 93, ODE lost 26 employees (20 scientific reviewers and 6 support staff) through resignation or retirement. This attrition was offset by the addition of 43 new employees (29 scientific reviewers, 14 of which are medical officers, and 14 support staff). This includes the acquisition of six staff members (3 scientific reviewers and 3 support staff) from the Office of Health Affairs.

Premarket Approval

During this fiscal year, we received 40 original PMAs, which continues a five year trend of decreasing original PMA receipts.

The total number of PMA actions(323), which includes filing decisions(53), review activity determinations(202) and approval decisions(68), dropped slightly from 332 last fiscal year but remained consistent with the previous four years with the exception of FY 91 during which time there were a record number of total PMA actions. The number of total PMA actions is a better indication of the level of output in the PMA area than just the number of approvals.

There were 24 PMAs that received final approval, double the number of approvals in FY 92. Another 23 original PMAs were found to be approvable, up from 18 last year. The number of PMA that were found to be not approvable also rose from 15 last year to 21 and there were no denials issued during FY 93. In total, the number of PMA decisions increased from 49 last year to 68 for this fiscal year.

Average FDA review time for original PMAs increased from 146 days in FY 92 to 328 days during FY 93. NonFDA review time also rose from 40 days in FY 92 to 109 days this fiscal year. As a consequence, total review time increased substantially from 186 days last year to 437 days in FY 93.

Total average elapsed time rose dramatically from 310 days last year to 799 days in the current reporting period. The FDA component of the total elapsed time nearly doubled from 236 days in FY 92 to 547 days but the nonFDA component more than tripled, from 74 days in FY 92 to 252 this year.

The total number of PMAs under review at the end of the fiscal year dropped somewhat from 164 to 150. The active PMAs under review at the end of this fiscal year numbered 94 compared to 87 last year, while those on hold were reduced a bit from last year, from 77 to 56. Unfortunately, the number of PMAs that were active and overdue increased from 36 last year to 45 at the end of FY 93.

During FY 93, PMA supplement activity was somewhat mixed when compared to the previous two years. The number of supplements received has fallen off significantly from last year's 606 to 395. The total number of PMA supplement actions, which includes panel track filing decisions(7), review activity determinations(256), and review decisions(569), dropped only slightly to 832 from last year's 849 total actions. This level of total actions is comparable to the total actions taken in the years prior to the FY 90 - FY 91 period, during which time PMA supplement actions were extraordinarily high. This number of total PMA supplement actions is a better indication of the level of output than just the number of PMA supplement approvals. There were a total of 354 PMA supplements that received final approval. These approvals included two "panel track" supplements.

The FDA average review time for PMA supplements went up from 113 days in FY 92 to 168 days this year and total average review time rose from 135 days last fiscal year to 203 days by the end of this year. In addition to the rise in FDA average review time, the nonFDA review time increased from 22 days in FY 92 to 35 days in FY 93. Average elapsed time also jumped from 167 days in FY 92 to 269 days this year, due to the increase in FDA elapsed time from 135 to 213 over the same period of time. NonFDA elapsed time also rose from 32 to 56 days in FY 93.

The 465 total number of PMA supplements under review at the end of this year represents a small reduction from last year's 485. The number of PMA supplements that were active and overdue, however, increased from 98 at the end of the last fiscal year to 173 at the end of this year. The

number of active supplements remained virtually the same as last year and the number of supplements on hold was reduced from 144 to 119 at the end of FY 93.

Investigational Devices

We received 241 original IDEs during FY 93, which is up slightly from the 229 received in FY 92. The same holds true for IDE decisions; the 248 original IDE decisions made during FY 93, up from 215 last year. This is expected; the output closely parallels the input because of the short turn around times involved with IDE reviews. The average FDA review time for original IDEs went down from 30 last year to 28 days, the lowest it has been since FY 88. Also, 97% of all original IDE decisions were completed within 30 days, identical to FY 92. The number of IDEs under review at the end of this fiscal year dropped to 14, down from 21 at the end of last year. There were three IDEs overdue at the end of the year.

Premarket Notification (510(k))

During this reporting period, ODE received 6,288 original 510(k)s as compared to 6,509 received during FY 92. There were also 3,940 510(k) supplements that came in during this fiscal year. Both original and supplemental 510(k)s total 10,228 submissions, down slightly from the 11,064 total 510(k) submissions received in FY 92. The 5,073 final decisions rendered on original 510(k)s during FY 93 was up from the 4,862 decisions rendered in FY 92.

FY 93 saw the continuation of a trend that began and was identified in the Annual Report for Fiscal Year 1991, the last year for which we issued a full report. Based on the trend of the average total review time for 510(k)s at the end of FY 91, we predicted, in the FY 91 Annual Report, that the total average review time for FY 92 might exceed 115 days and that it will probably continue to climb higher before it reaches a plateau. During FY 92 the total average review time increased to 126 days and continued to rise in FY 93 to reach 195 days by the end of the fiscal year.

A great deal of the rise in average review times was due to the factors discussed in earlier reports, e.g., programmatic changes, SMDA, oversight activities, etc. and the impact of the "reference list" program and the "Class III 510(k)/GMP" inspection program which became effective during FY 92 and FY 93, respectively.

During the past year, a number of management initiatives have been undertaken to reduce backlogs and stem the tide of rising review times. These initiatives include the triage procedures, refuse to accept policies, and expedited review. The benefits of these new policies and procedures plus the targeting of Center resources from other offices, as well as within ODE, to deal with 510(K)s are already starting to have an impact and we hope to see a turn-around in review times in the near future.

There were 5,157 510(k)s pending at the end of this fiscal year, which represents an increase over the 3,951 510(k)s that represented last year's end-of-year inventory. The number on hold, however, dropped slightly from 1,352 at the end of FY 92 to 1,335 at the end of this year. At the end of this reporting period, there were 1,894 510(k)s that were active and overdue, up from 331 in FY 92.

Guidance for Industry and Reviewers

The following listing of guidance documents includes documents that were issued in FY 92 as well as the current fiscal year because the Office of Device Evaluation did not issue a full annual report for FY 92. Inclusion of those documents in this report will provide a complete record for future reference.

Guidance Documents Issued During Fiscal Year 1992

- Nondisclosure of Financially Sensitive Information
- Training for Supervisors
- Urological Balloon Dilatation Catheters
- Lithotripsy
- Picture Archiving and Communications Systems
- Stentless Aortic Heart Valves
- TENS 510(k)s
- Guide for Intracranial Balloon Embolization Studies
- Liquid Germicides
- Resorbable Periodontal Barriers
- Hepatitis A
- Hepatitis B
- Chlamydia
- Cyclosporin
- Immunohistochemistry Products
- Parvovirus B19
- Fecal Occult Blood Tests
- IgM Antibodies
- Cholesterol In Vitro Diagnostic Devices Using Enzymatic Methodology
- Self-monitoring Glucose In Vitro Diagnostic Devices
- Estrogen (ER) or Progesterone (PGR) Receptors
- Immunoglobulins A, G, M, D, and E

Guidance Documents Issued During Fiscal Year 1993

- Telephone Communications Between ODE Staff and Manufacturers
- PMA summaries of Safety and Effectiveness and Federal Register Notices of PMA Approvals - Review by the Office of General Counsel (Revised)
- Overdue IDE Annual Progress Report Procedures
- 510(k) Additional Information Procedures
- Bone Densitometer
- Falloposcopes
- Biopsy Devices
- Ureteral Stents
- Urodynamic/Uroflowmetry Systems
- Diagnostic Ultrasound

- Penile Inflatable Implants
- Testicular Prosthesis
- Benign Prostatic Hyperplasia
- Home Uterine Activity Monitors
- Vasovasotomy Devices
- Interventional Cardiology Devices
- Peak Flow Meter Guidance
- Reviewer Guidance for Respiratory Devices
- Guide Cranial Electrical Stimulation Therapy Device Premarket Approval Content
- Replacement Heart Valves
- Calcium Phosphate Coating
- Suture Labeling
- Sterilizers
- Infusion Pumps
- Syringes and Needles
- Electronic Thermometers
- Intravenous Catheters
- Testing Orthopedic Implants
- Testing Biodegradable Fracture Fixation Implant Devices
- Testing Bone Anchor Devices
- Cemented, Semi-Constrained Total Knee Prostheses
- Preparation of 510(k)s for Orthopedic Devices
- Automated Endoscope Washers
- Surgical Gowns and Drapes
- Preparation of 510(k)s for Wound Dressing
- Preparation of an IDE for Interactive Wound and Burn Dressings
- Prosthetic Knee Intra-Articular Ligament Devices
- Anti-nuclear Antibodies
- Preparation of Premarket Submissions Implementing CLIA
- Allergen-Specific Immunoglobulin E
- Nucleic Acid Amplification-Based In Vitro Diagnostic Devices
- Mycobacteria Ssp
- Multifocal Intraocular Lens Guidance Document

Reclassification/Classification of Devices

During the year, we reclassified the following devices from class III to class II:

- the Hip-Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis; and,
- the Microsurgical Argon Laser for use in rhinology and Laryngology.

In addition to the foregoing final actions, FDA published proposed rules in the *Federal Register* which announced the opportunity to request the reclassification of the Nonroller-Type Cardiopulmo-

nary Bypass Blood Pump and Cranial Electrotherapy Stimulators. In addition, we received three petitions to reclassify the Nd:YAG Lasers for Iridotomy, the Ostomy Bag and Associated Devices, and the Contraceptive Cervical Cap.

The Dental Devices Panel recommended the classification of the Glenoid fossa and Mandibular condyle implants, Electrical Dental anesthesia devices and Root apex locators into Class III, at a panel meeting in February, 1993.

Call for PMAs for Pre-Amendments Devices

During this fiscal year, ODE published 515(b) proposed rules in the Federal Register for the following devices:

- Silicone Inflatable Breast Prosthesis, 58 FR 3436 (January 8. 1993)
- Testicular Prosthesis,58 FR 4116, (January 13. 1993)
- Penile Inflatable Implant, 58 FR 25902, (April 28, 1993)
- Nonroller-Type Cardioplumonary Bypass Blood Pump, 58 FR 36290, (July 6,1993)
- Cranial Electrotherapy Stimulators, 58 FR 45865, (August 31, 1993)

Advisory Panel Activities

ODE held 20 medical device advisory panel meetings during the past year. The meetings covered matters such as implantable defibrillators, testicular and penile implants, home uterine activity monitors, multifocal intraocular lenses, human genetic in vitro diagnostic devices, use of prostate specific antigen as an early detection of prostate cancer, non-thermal effects of diagnostic ultrasound, pedicle screw spinal fixation devices, and TMJ implants. ODE also held its first workshop titled, "Design and Conduct of Clinical Trials for the Evaluation of Cardiovascular Devices." During this past year ODE conducted a meeting of the Advisory Panel Chairpersons (first of its kind) to announce our new management initiatives. As part of the Institute of Medicine's report titled, "Food and Drug Administration Advisory Committees," ODE began to implement some of the recommendations identified in the report. ODE continued to conduct formal training sessions for new panel members. Periodic group meetings with the Executive Secretaries were held throughout the year.

ODE Integrity Program

During the last two fiscal years, ODE issued two Integrity Blue Book Memoranda:

- Nondisclosure of financially Sensitive Information - I92-1, March 5, 1992
- Telephone Communications Between ODE Staff and Manufacturers - I93-1, January 29, 1993

During FY 93 it was necessary to request data audits on more than 30 submissions. These directed data audits are in addition to the routine data audits conducted by the Office of Compliance. Some of these requests for directed data audits were based, in part, upon the following factors:

- Internal inconsistencies within the submission that could not be attributed to harmless error, e.g., patient reports compared to summary data;
- Scientifically implausible data on physical attributes of the device or its components, e.g., viscosity ranges, temperature ranges; etc.;
- Contradictory information provided by scientific/clinical researchers, e.g., who authored supporting articles or conducted supporting research;
- Data inconsistent with the scientific/professional literature, e.g., the total number of patients treated with a device;
- Information provided by employees of the applicant, e.g., the maintenance of a double set of records; and,
- Information obtained from official documents, e.g., court trial records: complaints, affidavits, etc.

This year saw the issuance of the first letter to a medical device firm by the Center for Devices and Radiological Health pursuant to FDA's "Application Integrity Program" (AIP). The AIP was formerly known as the "Fraud Policy". Under the AIP, the substantive review of all pending and future submissions by the firm to whom the AIP letter is issued is suspended until the firm undertakes an internal audit and implements an acceptable corrective action plan.

Freedom of Information Requests

ODE received 973 Freedom of Information requests during FY 93.

Publications

During FY 93, the Information Clearance Committee cleared three abstracts authored by ODE staff for publication in professional and scientific journals and 18 presentations to be delivered by ODE staff at professional and scientific and trade association meetings.

Program Management and Support

Extensive training, both in-house and off-site, was provided in FY 93 to meet the needs of ODE employees. Input was obtained from ODE staff members, managers, and industry representatives to identify the areas where training was most needed.

With a recent influx of PCs provided through Center funding we finally received enough PCs to provide one to every person in ODE needing a PC. This purchase will eliminate equipment incompatibility and remove the need to convert documents from one word processing format to another.

The Office of Information Systems (OIS) continued the conversion of ODE tracking systems to the Oracle database management system with the conversion of two ODE tracking systems. In March 1992, the IDE tracking system was converted to Oracle and in July 1993, the 510(k) system was converted. This conversion is part of the OIS goal of an integrated information system implemented on common hardware and with the same database management system.

The number of documents on IMAGE increases daily. At the end of FY91, 3,987 510(k)s were loaded on optical disk. At the end of FY93, 30,772 510(k)s, 297 PMA originals, and 937 PMA supplements were available for viewing on IMAGE. The number of PMAs available for viewing will increase as pre-1988 PMAs are readied for scanning. Initial scanning of IDEs began at the end of FY93.

To make documents available for viewing early in the review process, ODE has initiated scanning documents on-arrival starting with PMA originals received after October 1, 1993. On-arrival scanning will expand to cover 510(k)s and IDEs as ODE moves from a paper-bound system to one embracing more electronic storage.

The Office of Information Systems, working with the Centers for Disease Control and Prevention (CDC), installed a CLIA PC-based application within the Division of Clinical Laboratory Devices which allows the viewing of complexity determinations from CDC CLIA databases.

The major office management event of this fiscal year was the reorganization of ODE from seven to five divisions. The new organizational structure is an attempt to respond to both growth and technological change that have resulted in an increased and diversified workload. These changes provide greater scientific and technical focus, better alignment of functions and staff, and improved management control and more effective supervision. Review procedures have been enhanced by the improved management structure and the proper realignment of product specialties.

Despite a significantly reduced office automation budget, we continued to build upon a foundation of installed equipment to improve office automation capabilities. We received PCs that were ordered in FY 90 which expanded our base of PCs. This expanded base helped reduce the equipment incompatibilities between PCs and DECmates and provided a computer capable of word processing to each individual needing this equipment. We expanded our LAN capabilities through the purchase of LAN hardware and commenced the process of having 510(k)s and recently completed PMAs scanned to the CDRH IMAGE system.

ANNUAL REPORT
OFFICE OF DEVICE EVALUATION
FISCAL YEAR 1993

I. INTRODUCTION

The Office of Device Evaluation(ODE) in the Food and Drug Administration's(FDA) Center for Devices and Radiological Health is responsible for the program areas through which medical devices are evaluated and cleared for human clinical trials or marketing. This report provides information about major programs administered by ODE during Fiscal Year 1993(FY 93), beginning on October 1, 1992 and running through September 30, 1993. Part II discusses the ODE workload and resources available and Part III examines the performance and activities of the premarket approval, investigational device exemption, and premarket notification programs. Part III also contains comparative performance data from previous fiscal years and trend analyses. Part IV covers procedure and policy guidance and other management initiatives to further implement our policy and program goals and to streamline our procedures. This part also includes device reclassification, freedom of information, and PMAs for pre-Amendments devices under Section 515(b). Part V covers various aspects of ODE resources. Finally, Part VI consists of statistical tables that contain the data on program performance for FY 93.

II. OVERALL WORKLOAD AND RESOURCES

A. Workload

During FY 93 ODE received a total of 16,869 submissions. This represents a decrease of 1,217 from the all time high of 18,086 total submissions received in FY 92. The FY 93 total represents the third largest total number of submissions ever received during one fiscal year. Since FY 88, the total number of submissions has fluctuated between 15, 363 and 18,086. This year's total is in line with our experience in earlier fiscal years.

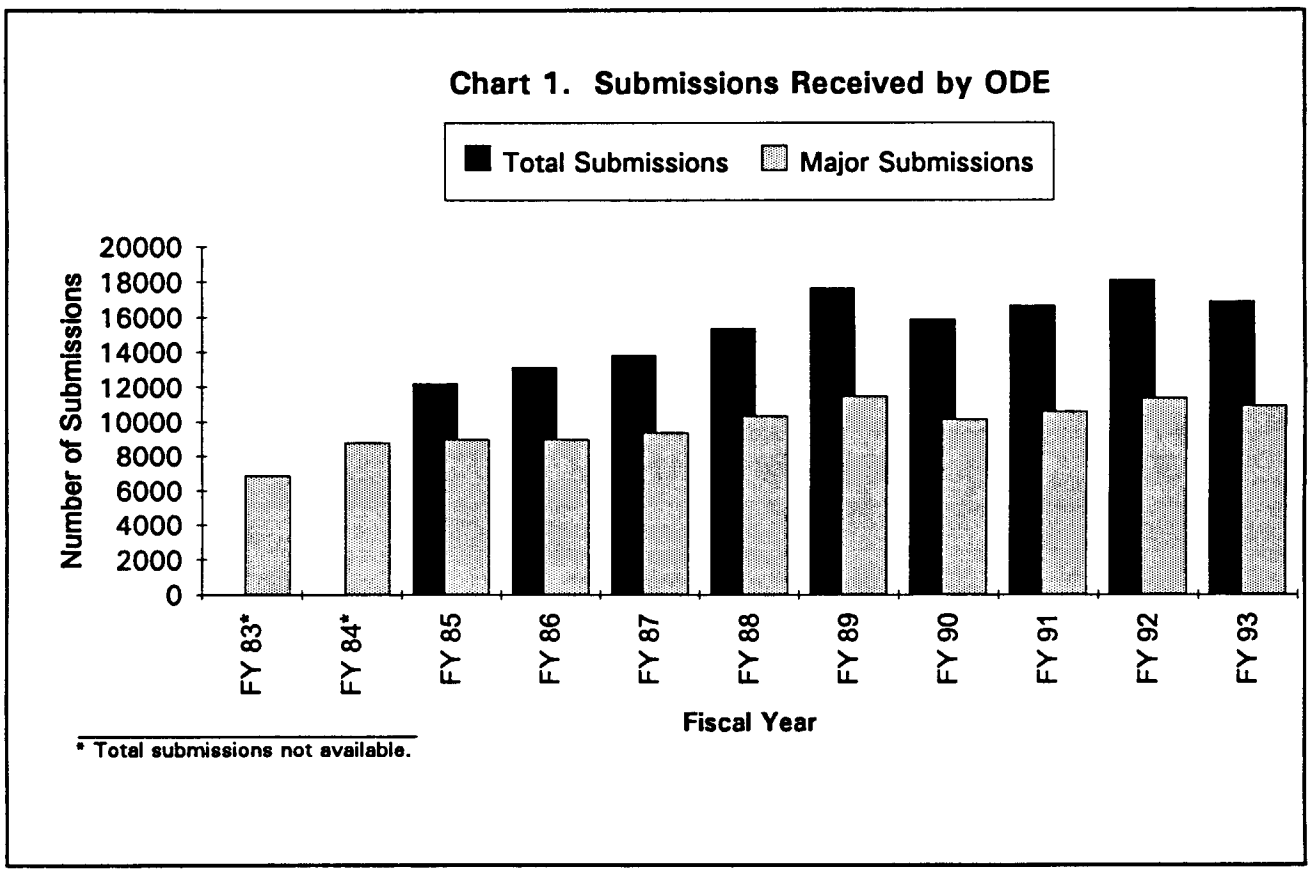
The same is true for the number of major submissions: PMAs, PMA supplements, IDEs, IDE amendments, IDE supplements, and 510(k)s. We received a total of 10,952 major submissions during FY 93, a decrease of 398 from the record number of 11,350 major submissions received in FY 92.

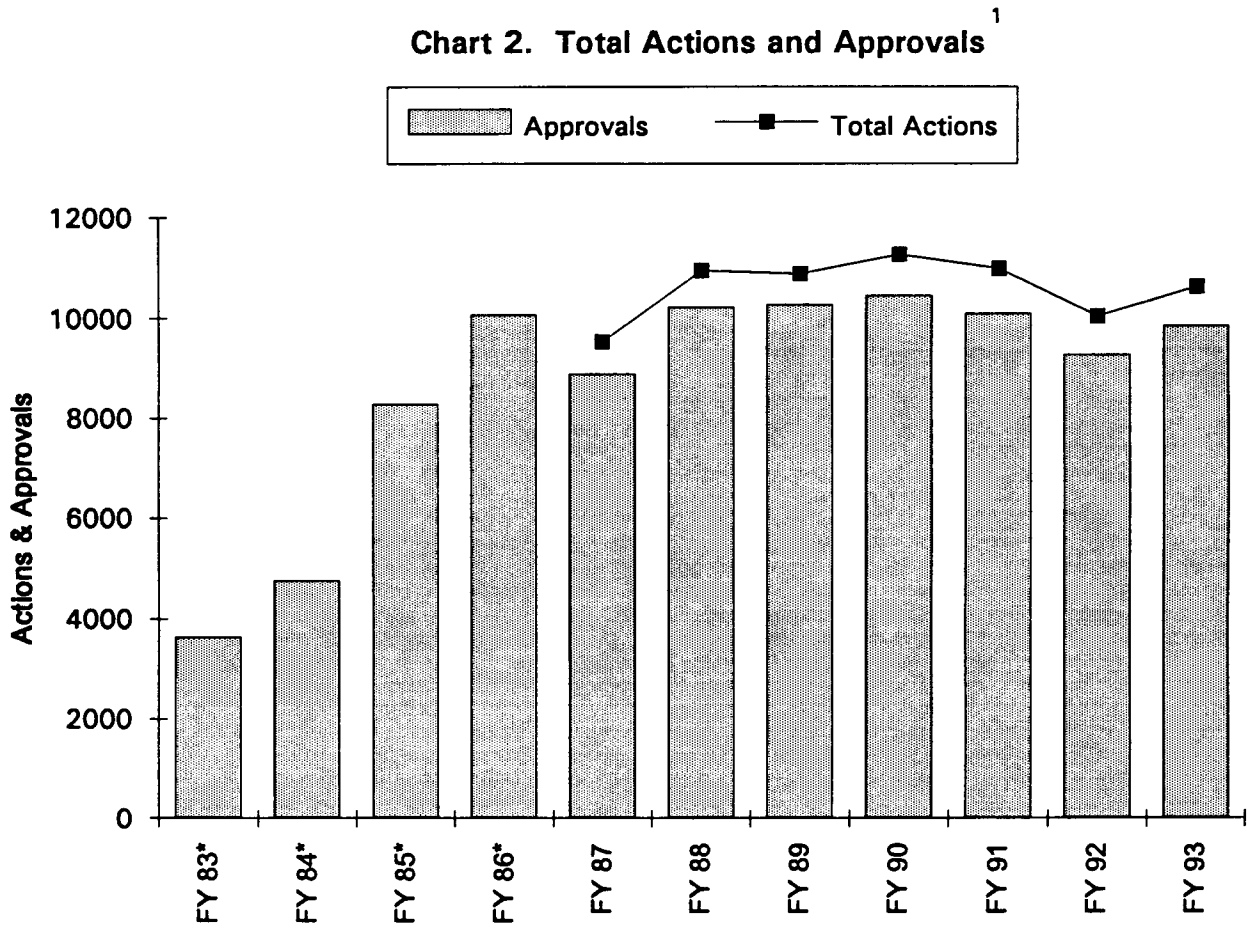
On the output side, ODE reviewed 9,837 major submissions, which represents an increase of 588 from the 9,249 major submissions reviewed during FY 92. This represents the reversal of the previous two-year trend of decreasing numbers of major submissions reviewed.

Along with the large number of submissions being received, there are related program factors that have increased the difficulty and the time required to process submissions. The specific factors are discussed under each program area, as appropriate, and include continuing implementation of the SMDA, 510(k) exemptions, participating in the Congressional hearing process, cooperating with program audits and oversight activities. All of these activities have had a negative impact on ODE staff productivity. The time consumed by some of these activities is transitory but some of them, such as implementation of the new requirements of the SMDA, will have an enduring effect. This can be seen in Chart 9, "Major Reviews and Total Actions per FTE," which demonstrates a reduction in the number of submissions completed annually per FTE since FY 90. This fiscal year we experienced a leveling-off of this ratio, but it is too early to tell whether this is the start of a new trend.

B. Resources

Unlike previous years, there was no FTE ceiling allocated within ODE for FY 93. The actual FTEs used during this fiscal year was 273, an increase of 10 over the number used in FY 92.





* Total Actions not available for these fiscal years.
1. For "Major Reviews" and "Total Actions" , see Statistical Tables.

ODE ended the year with 291 employees on board, an increase of 24 from the 276 at the end of last year.

In FY 93, ODE lost 26 employees (20 scientific reviewers and 6 support staff) through resignation or retirement. This attrition was offset by the addition of 43 new employees (29 scientific reviewers, 14 of whom are medical officers, and 14 support staff). This includes the acquisition of six staff members (3 scientific reviewers and 3 support staff) from the Office of Health Affairs.

Chart 3. ODE Full Time Equivalents

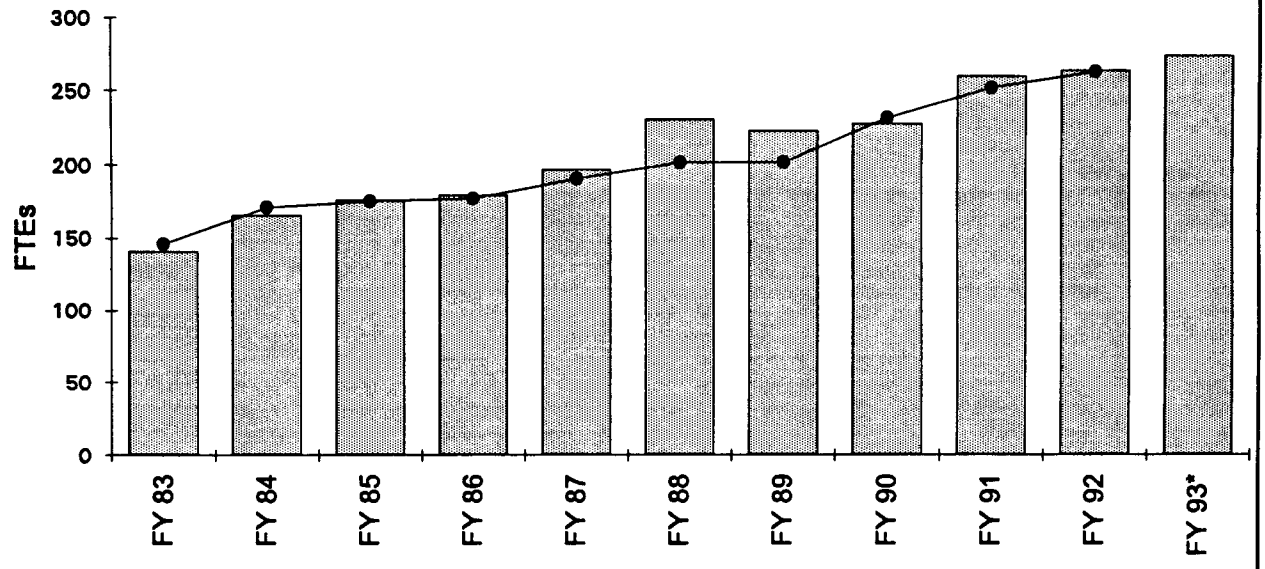


Chart 4. Major Submissions vs. FTEs

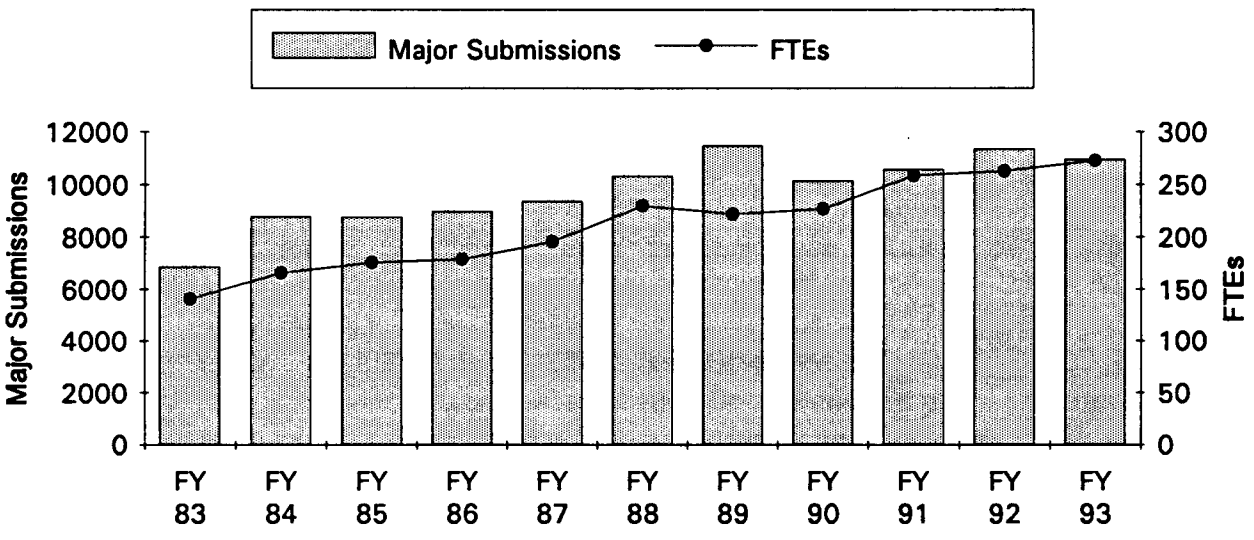


Chart 5. Major Reviews per FTE

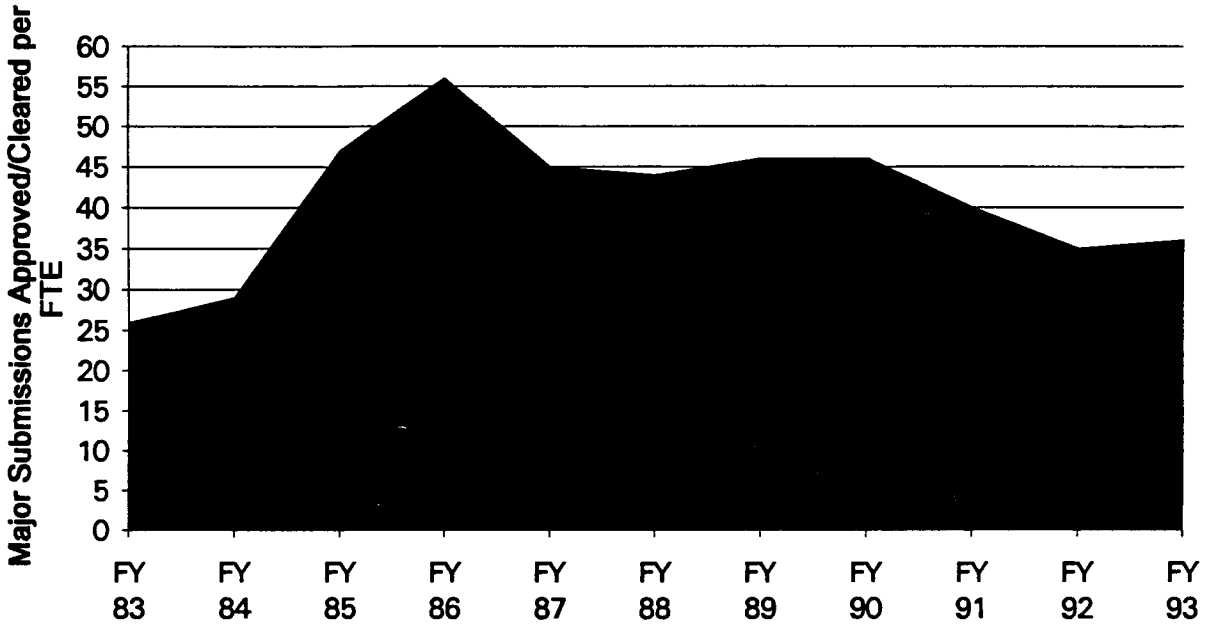
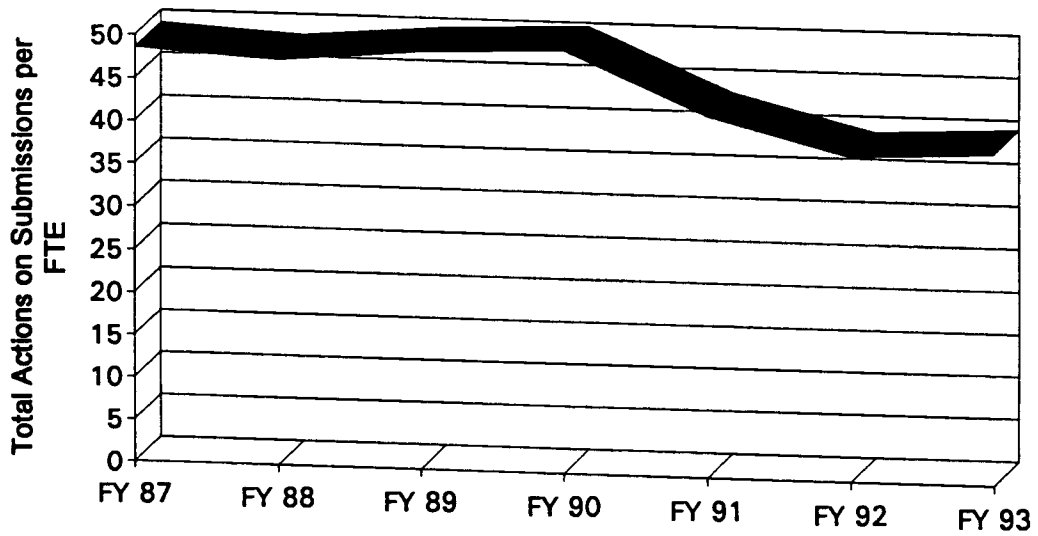


Chart 6. Total Actions per FTE



III. MAJOR PROGRAM ACTIVITIES AND PERFORMANCE

This section is divided into five subparts. The first three subparts, A - C, describe and analyze program performance in the three areas that are ODE's primary responsibility, i.e., Premarket Approval, Investigational Devices Exemption, and Premarket Notification. Subpart D discusses a number of policy and program changes designed to improve the quality, efficiency and timeliness of reviews and compliance with the requirements of the PMA, IDE, and 510(k) programs. Subpart E identifies significant medical devices cleared for marketing during this fiscal year. Reference data discussed for the three major program areas and definitions or explanations of the terms used are contained in the statistical tables in Part VI of the report. Comparative data are displayed graphically throughout the report.

A. Premarket Approval

1. Premarket Approval Applications (PMAs)

Under the Federal Food, Drug, and Cosmetic Act (the act) and the FDA regulations, *Code of Federal Regulations, Title 21* (the regulations), a manufacturer or others must submit a PMA for FDA review and approval before marketing certain new devices. The PMA must provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufac-

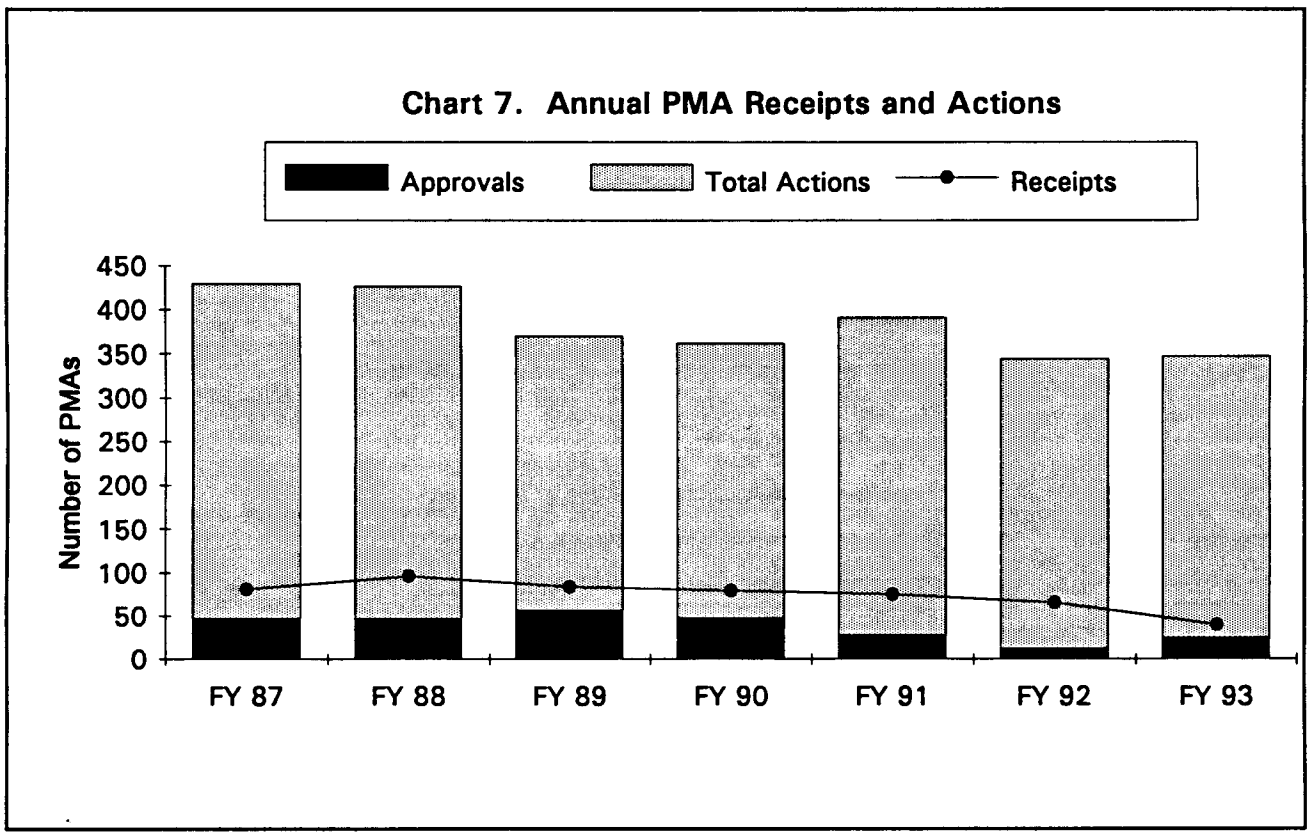
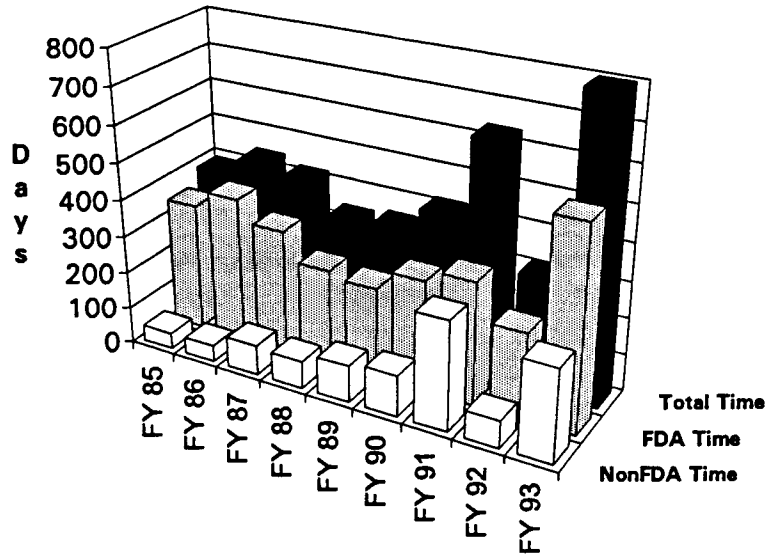


Chart 8. Average Elapsed Time for PMA Approvals



tured in accordance with current good manufacturing practices. As part of its review process FDA may present the PMA to an expert advisory panel for its recommendations on the application. After obtaining the panel recommendations, the agency makes a determination to approve the PMA, deny it, or request additional information. If the PMA is approved or denied approval, FDA must publish a notice in the *Federal Register* to inform the public of the decision and to make available a summary of the safety and effectiveness data upon which the decision is based.

During this fiscal year, we received 40 original PMAs, which continues a five year trend of decreasing original PMA submissions.

The total number of 323 PMA actions, which includes 53 filing decisions, 202 review activity determinations, and 68 approval decisions, dropped slightly from 332 last fiscal year but remained consistent with the previous four years, with the exception of FY 91 during which time there was a record number of PMA actions. This total number of PMA actions is a better indication of the level of output in the PMA area than is the number of approvals alone.

Twenty four PMAs received final approval, double the number of approvals in FY 92. Another 23 original PMAs were found to be approvable, up from 18 last year. The number of PMAs that were found to be not approvable also rose from 15 last year to 21 and there were no denials

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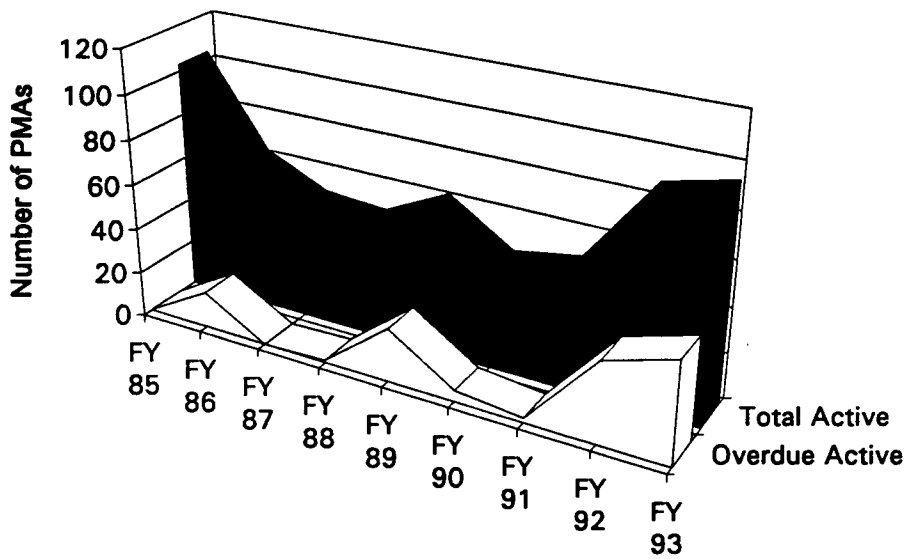
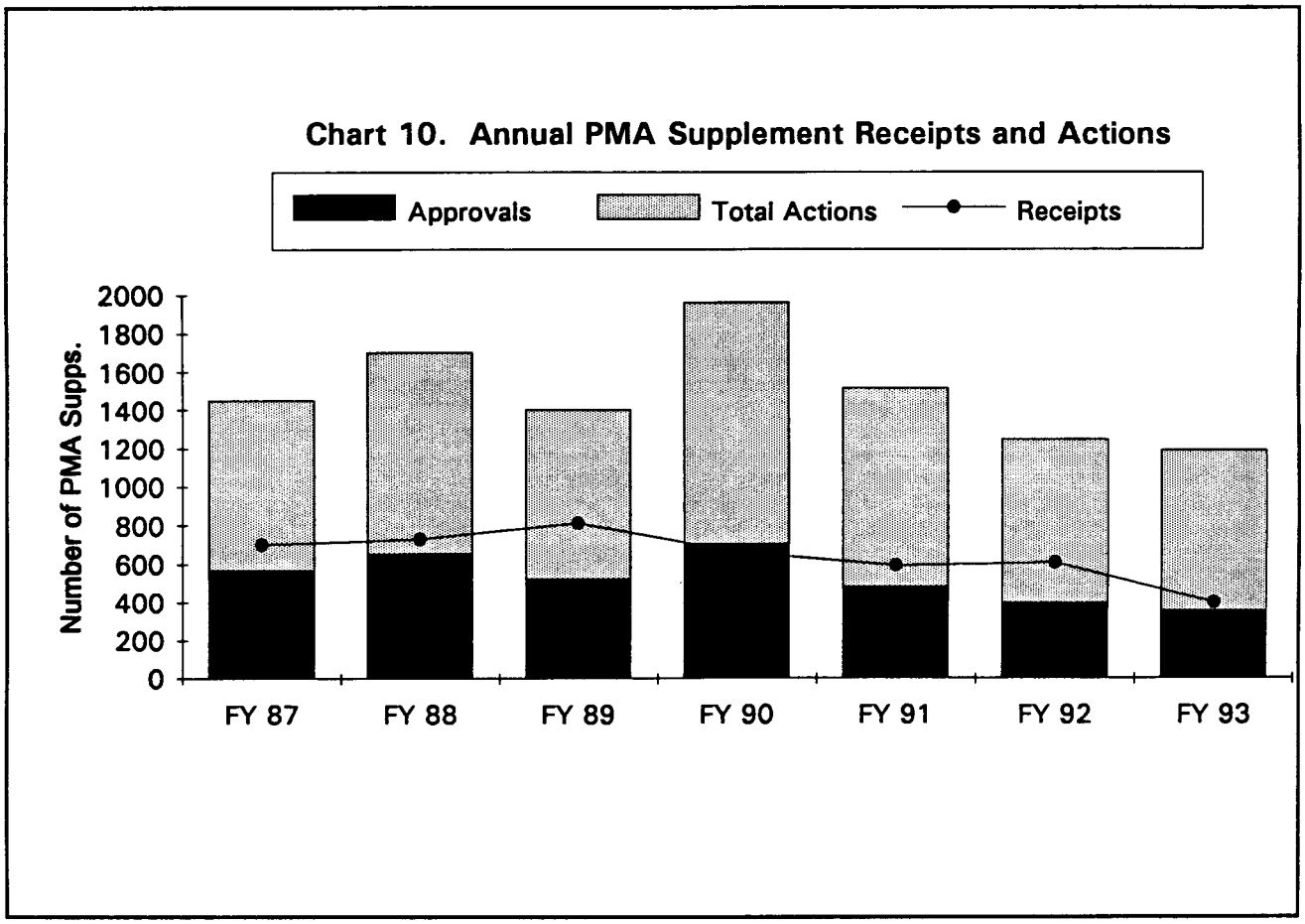
Chart 9. End-of-Year Active PMAs



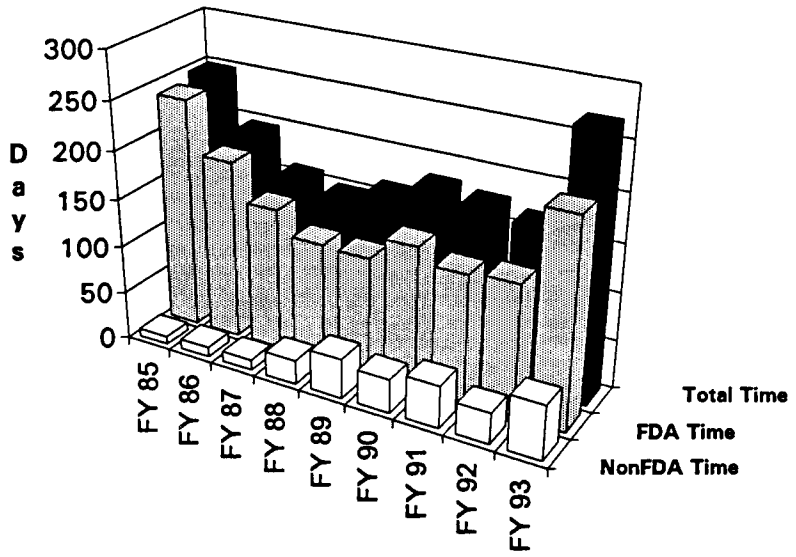


The total number of PMAs under review at the end of the fiscal year dropped somewhat from 164 to 150. The active PMAs under review at the end of this fiscal year numbered 94 compared to 87 last year, while those on hold were reduced a bit from last year, from 77 to 56. Unfortunately, the number of PMAs that were active and overdue increased from 36 last year to 45 at the end of FY 93.

2. PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made, for example, changes to the device, its labeling or packaging, or the manufacturing processes used in its production. Unless prior approval is expressly not required by the PMA regulation, those changes that affect the safety or effectiveness of the device require FDA approval. FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology.

Chart 11. Average Elapsed Time for PMA Supplement Actions



During FY 93, PMA supplement activity was somewhat mixed when compared to the previous two years. The number of supplements received has fallen off significantly from last year's 606 to 395. The total number of PMA supplement actions, which includes seven panel track filing decisions, 256 review activity determinations, and 569 review decisions, dropped only slightly to 832 from last year's 849 total actions. This level of total actions is comparable to the total actions taken in the years prior to the FY 90 - FY 91 period, during which time PMA supplement actions were extraordinarily high. This total number of PMA supplement actions is a better indication of the level of output than is the number of PMA supplement approvals.

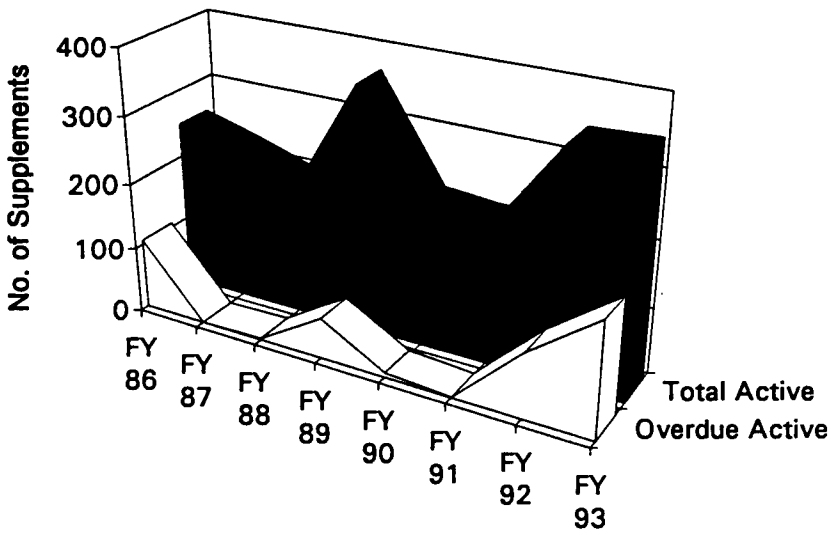
There was a total of 354 PMA supplements that received final approval. These approvals included two "panel track" supplements. Panel track supplements require the full administrative procedures normally associated with original PMAs, i.e., Panel review, preparation of a summary of safety and effectiveness data, and publication of a *Federal Register* notice.

The FDA average review time for PMA supplements went up from 113 days in FY 92 to 168 days this year and total average review time rose from 135 days last fiscal year to 203 days by the end of this year. In addition to the rise in FDA average review time, the non-FDA review time increased from 22 days in FY 92 to 35 days in FY 93.

Average elapsed time also jumped from 167 days in FY 92 to 269 days this year, due to the increase in FDA elapsed time from 135 to 213 over the same period of time. Non-FDA elapsed time also rose from 32 to 56 days in FY 93.

The 465 total number of PMA supplements under review at the end of this year represents a small reduction from last year's 485. The number of PMA supplements that were active and overdue, however, increased from 98 at the end of the last fiscal year to 173 at the end of this year. The number of active supplements remained virtually the same as last year and the number of supplements on hold was reduced from 144 to 119 at the end of FY 93.

Chart 12. End-of-Year Active PMA Supplements



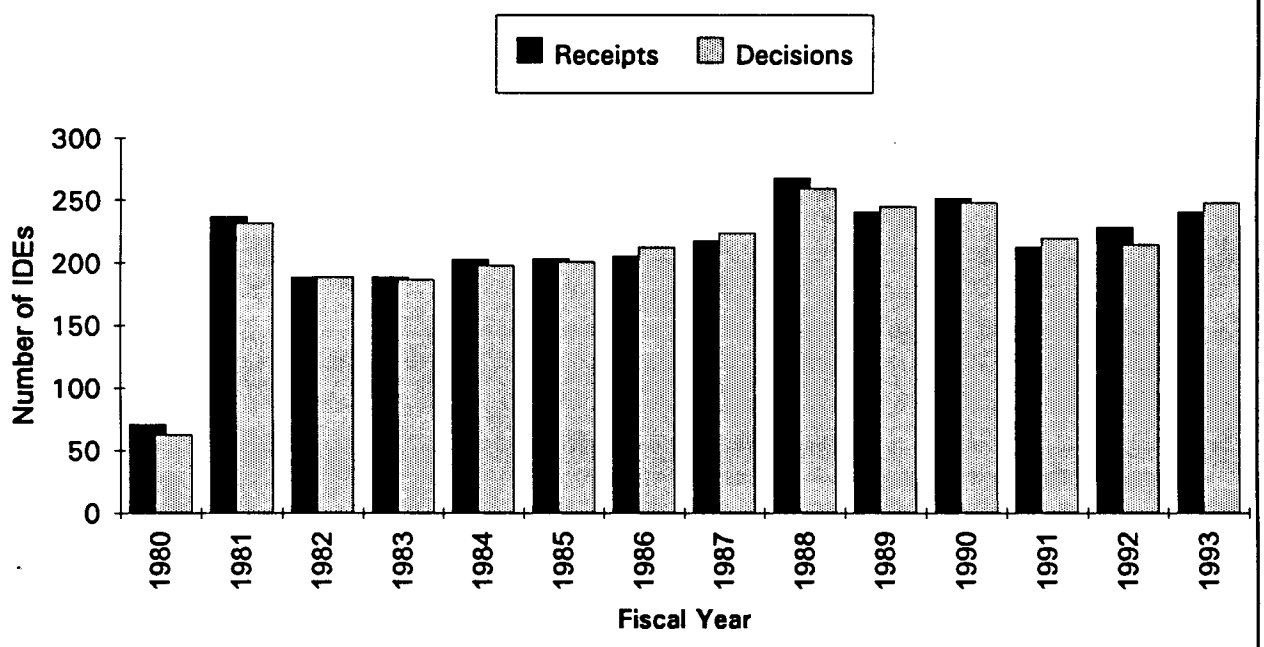
B. Investigational Devices

1. Investigational Device Exemptions (IDEs)

Under the act and regulations, a person may sponsor the clinical investigation of a medical device to establish its safety and effectiveness. Before conducting a clinical trial, however, the sponsor must obtain the approval of an institutional review board (IRB). If the investigational device study presents a significant risk to subjects, the sponsor also must obtain FDA's approval of an investigational device exemption application (IDE). The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject informed consent, device labeling, cost of the device, and other matters related to the study. FDA has 30 days from the date of receipt to approve or disapprove an IDE application.

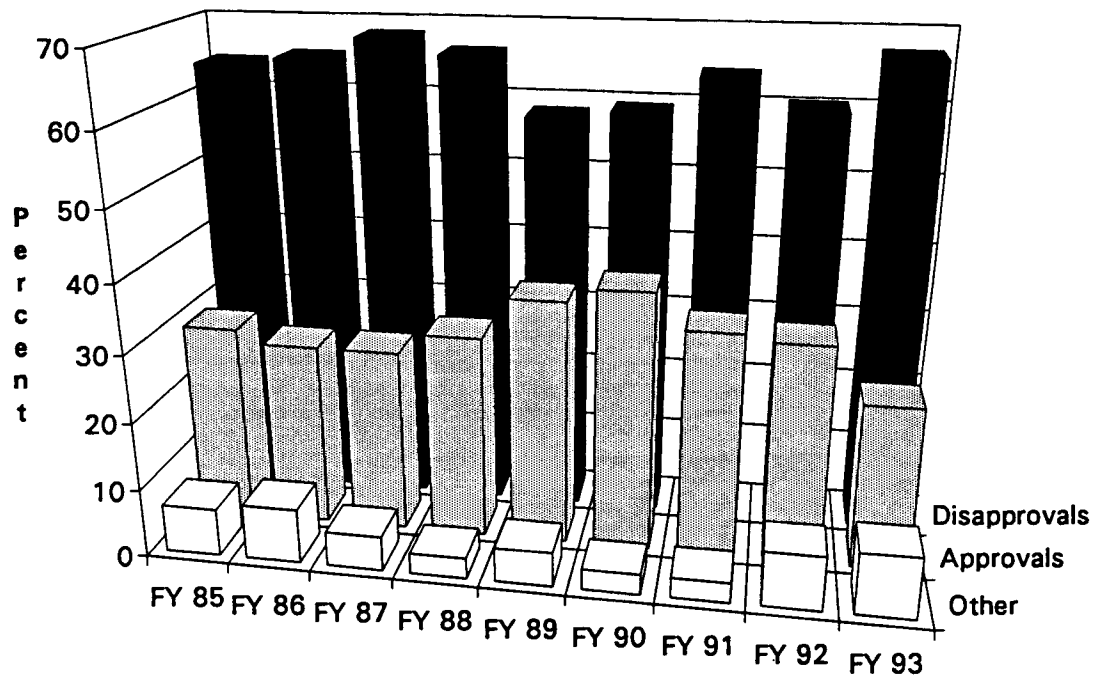
We received 241 original IDEs during FY 93, which is up slightly from the 229 received in FY 92. The same holds true for IDE decisions; the 248 decisions made on original IDEs during FY 93, was up from 215 last year. This is to be expected; the output closely parallels the input because of the short turn around times involved with IDE reviews. The average FDA review time for original IDEs went down from 30 days last year to 28 days, the lowest it has been since FY 88. Also, 97% of all original IDE decisions were completed within 30 days, identical to FY 92. The number of IDEs under review at the end of this fiscal year dropped to 14, down from 21 at the end of last year. There were three IDEs overdue at the end of the year.

CHART 13. Annual Original IDE Receipts and Decisions



Of the total decisions made on original IDEs this year, the percentage of decisions that resulted in approval has dropped for the third consecutive year, from 32% in FY 92 to 24% in FY 93. This is the first time the percentage of approvals has dropped below 30% since FY 87. It is important that the device industry and ODE do all that they can to keep this rate of approval as high as possible because of the savings in cost and time for the FDA and industry alike when IDEs are approved upon their first submission.

Chart 14. Percentages of Types of Actions on Original IDE Decisions



2. IDE Amendments

Although not provided for in the IDE regulations, we refer to all submissions related to an original IDE that has been submitted but not approved as an IDE amendment. Submissions related to an IDE after it is approved are supplemental applications under the regulations. Identification of IDE amendments enables FDA to track each IDE from the time it is originally submitted to the time it is approved.

During this fiscal year we received 320 amendments, up slightly from 297 during the last fiscal year. This was the second largest number of amendments ever received in a fiscal year. We made 324 decisions on amendments, up from 297 last year. These decisions were broken down into: 93 approvals(29%); 131 disapprovals(40%); and 100 other administrative actions(31%). Ninety-six percent of these decisions were made within 30 days. The number of IDE amendments pending at the end of this fiscal year was 16, down from the 21 that were pending at the end of last year, and two of these were overdue.

Each amendment is associated with an original IDE. Thus, the approval of an amendment constitutes the approval of an original IDE and the proposed investigation may begin. During FY 93, the 93 approved amendments were related to 88 original IDEs. The additional 5 amendments, above the 88 original IDEs, were related to some of the same original IDEs and were approved simultaneously. The average number of amendments per originally disapproved IDE that was approved in FY 93 was 2.2.

It took an average total time of 212 days to approve amended IDEs this year, up from the 188 days last year and the first time it has exceeded 200 days. This total approval time consisted of 83 days for FDA time, up from 79 days last year, and 129 days for non-FDA time, up from 109 days in FY 92.

Chart 15. Average Approval Time for IDEs with Amendments

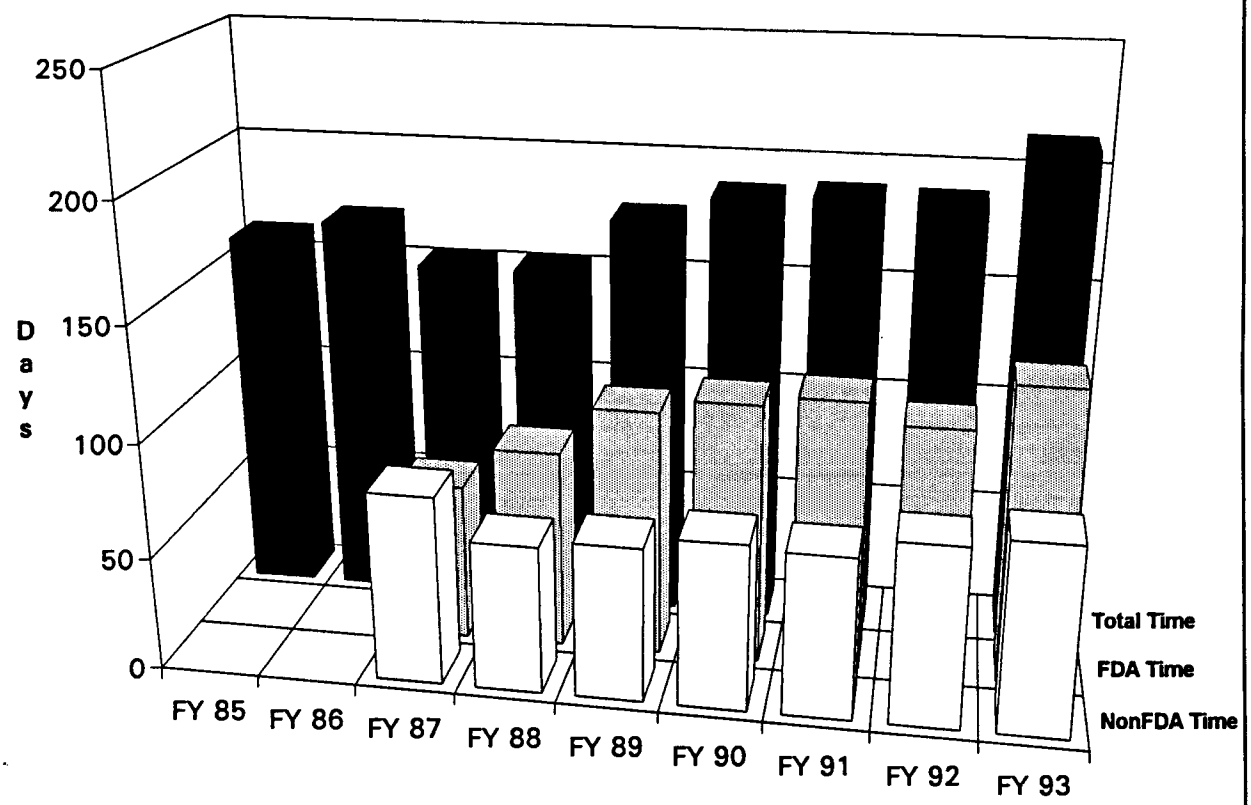
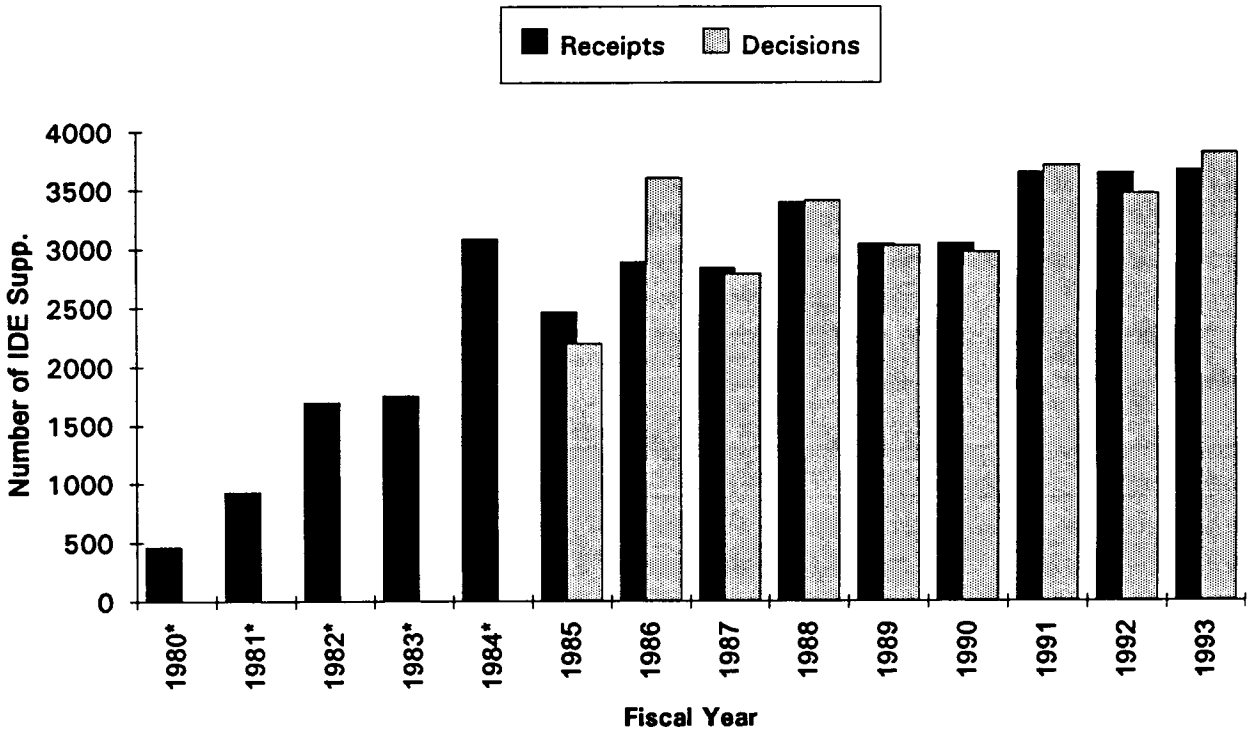


Chart 16. Annual IDE Supplement Receipts and Decisions



* Data on Decisions Not Available.

3. IDE Supplements

The IDE regulation requires that the sponsor of an investigation of a significant risk device submit a supplemental application if there is a change in the investigational plan, where such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. Supplemental applications are also required for the addition of investigational sites. The supplements must update information previously submitted in the IDE application, including any modifications to the investigation.

This regulation also requires the submission of various reports, which are logged in as supplements to IDE applications. These include reports on unanticipated adverse effects of the device; recall and device disposition; failure to obtain informed consent; and annual progress reports, final reports, investigator lists, and other reports requested by FDA.

We received 3,668 IDE supplements during FY 93, a record number of supplements which represents an increase of 24 submissions over the 3,644 received in FY 92. The number reviewed, 3,814, also represents a record number - up 345 from fiscal year 1992. The number under review at the end of FY 93 was reduced to 213 from last year's 359. There were eight overdue supplements at the end of the year, up from four at the end of FY 92 and the percentage of supplements reviewed within the 30-day statutory time frame dropped slightly from 99% in FY 92 to 97% in FY 93. The average review time for completing the review of IDE supplements rose to 24 days, the third year in a row in which we have seen an upward trand.

C. Premarket Notification (510(k))

At least 90 days before placing a medical device into commercial distribution, a manufacturer must submit to FDA a premarket notification, commonly known as a 510(k). In addition to other information concerning the device, e.g., a description of the device, a 510(k) summary or 510(k) statement, etc., the 510(k) must also include data to substantiate any claim that the device is "substantially equivalent" to a legally marketed device that is not subject to premarket approval. A substantially equivalent device is marketed subject to the same regulatory controls as the device to which it is substantially equivalent. If the device is found to be not substantially equivalent, the manufacturer may submit a petition for reclassification of the device from class III to class I or II, submit a PMA to market the device, or submit an IDE to conduct a clinical investigation to obtain data or information to support a new 510(k) or PMA.

During this reporting period, ODE received 6,288 original 510(k)s compared to 6,509 in FY 92, and 3,940 510(k) supplements. Original and supplemental 510(k)s totaled 10,228 submissions, down slightly from the 11,064 received in FY 92. The 5,073 final decisions rendered on original 510(k)s during FY 93 was up from the 4,862 rendered in FY 92.

There are two average review times that traditionally have been reported for 510(k)s. The average review time based on total time is calculated, in part, by totaling all the times each 510(k) is reviewed by FDA plus all of the times the 510(k) is on hold while it is under revision by the submitter. This average is useful to manufacturers who wish to estimate how long it may take to get a final decision from the time a 510(k) is originally submitted. The FDA average review time is based only on the total of all of the times each 510(k) is reviewed by FDA. Both of these average review times rose dramatically during FY 93. The total average review time rose from 126 days in FY 92 to 195 days for FY 93 and the FDA review time went up to 162 days from 102 days in FY 92.

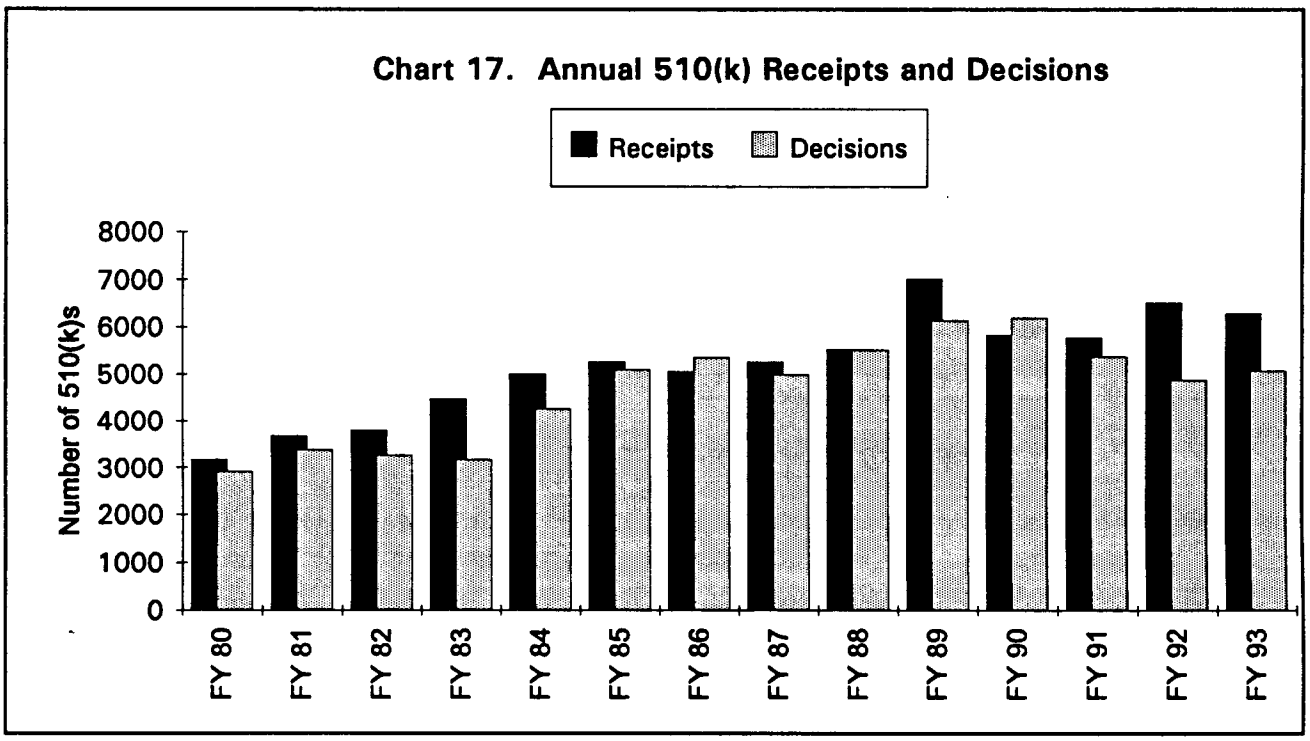


Chart 18. Average 510(k) Review Time

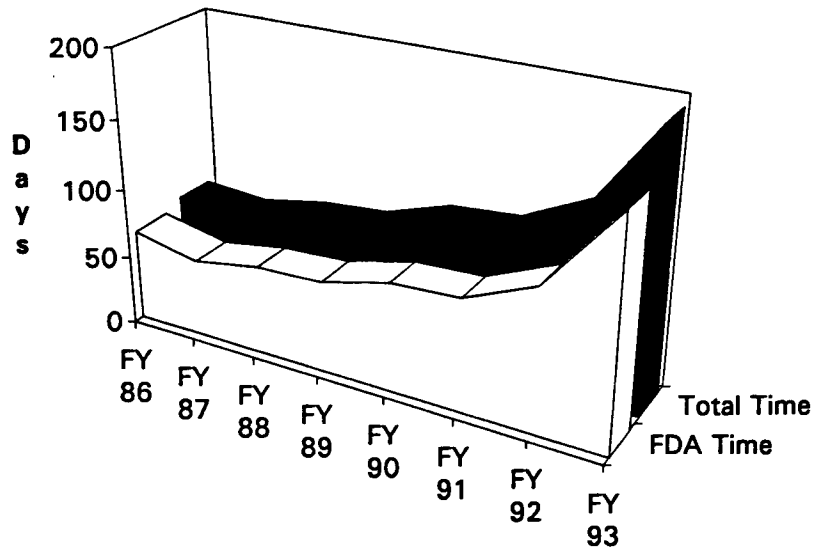
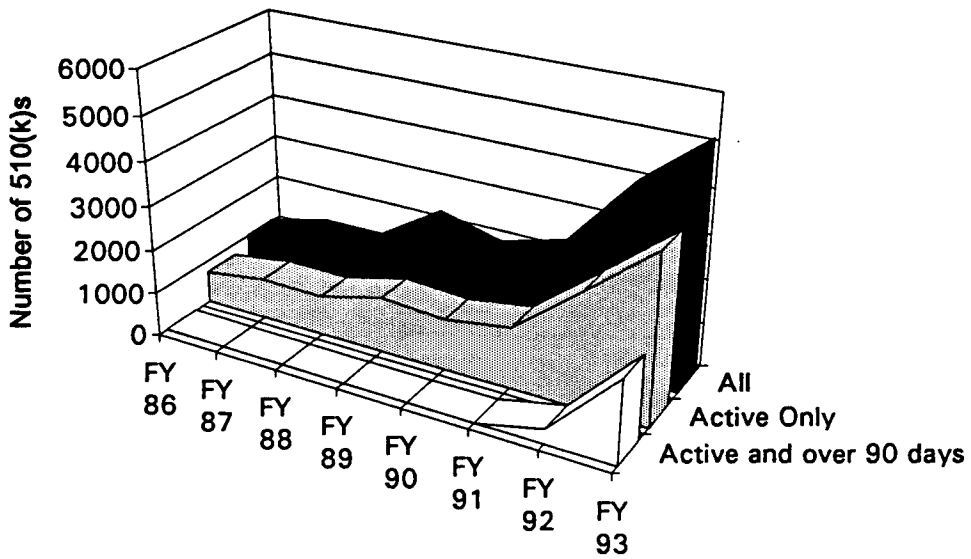


Chart 19. Pending 510(k)s



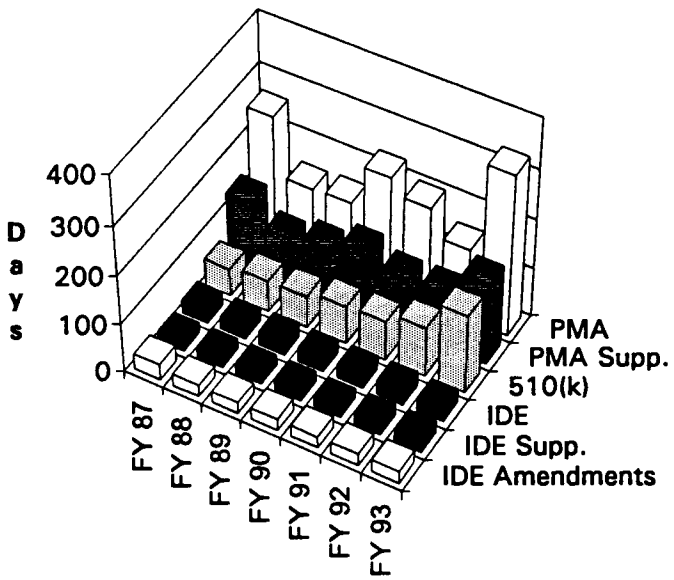
FY 93 saw the continuation of a trend that was identified in the Annual Report for Fiscal Year 1991, the last year for which we issued a full report. Based on the trend of the average total review time for 510(k)s at the end of FY 91, we predicted, in the FY 91 Annual Report, that the total average review time for FY 92 might exceed 115 days and that it would probably continue to climb higher before it reached a plateau. During FY 92 the total average review time increased to 126 days and continued to rise in FY 93 to 195 days by the end of the fiscal year.

A great deal of the rise in average review times was due to the factors discussed in earlier reports, e.g., programmatic changes, SMDA, oversight activities, etc., and the impact of the "reference list" program and the "Class III 510(k)/GMP" inspection program, which became effective during FY 92 and FY 93, respectively. These are discussed below in Subpart D.

During the past year, however, a number of management initiatives have been undertaken to reduce backlogs and stem the tide of rising review times. These are discussed below, in Part III. A., Center Management Initiatives, and include the triage procedures, refuse to accept policies, and expedited review. The benefits of these new policies and procedures, plus the targeting of Center resources from other offices as well as within ODE to deal with 510(K)s, are already starting to have an impact and we hope to see a turn-around in review times in the near future.

There were 5,157 510(k)s pending at the end of this fiscal year, which represents an increase over the 3,951 510(k)s that represented last year's end-of-year inventory. The number on hold, however, dropped slightly from 1,352 at the end of FY 92 to 1,335 at the end of this year. At the end of this reporting period, there were 1,894 510(k)s that were active and overdue, up from 331 in FY 92.

Chart 20. Average FDA Review Times



D. Major Program and Policy Initiatives

During FY 93, ODE instituted a number of policy and program changes designed to improve the quality, efficiency and timeliness of reviews and to improve compliance with the requirements in the PMA, IDE and 510(k) programs.

1. Center Management Initiatives

On June 30, the Center issued five management initiative issue papers to streamline and improve the efficiency of the submission review process. These issue papers were first released at a meeting of the Chairpersons of ODE's Advisory Panels. Representatives of the trade press and industry associations were also present. The five management initiatives were:

- "Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources." The purpose of this "triage" proposal is to establish a three tier system using risk assessment to more effectively manage the review workload and for allocating review resources.

- "Expedited Review." The purpose of this proposal is to establish criteria and procedures under which expedited review would apply to PMAs and 510(k)s based upon the device's potential for clinically meaningful benefit as compared to existing modalities or when the new medical device promises to provide a revolutionary advance over currently available alternatives.

- "Premarket Approval Application Refuse to File Policy." The purpose of this policy is to establish procedures under which a PMA that does not meet a minimum threshold of acceptability will not be accepted for substantive review.

- "Investigational Device Exemption Refuse to Accept Policy." The purpose of this policy is to establish procedures under which an IDE that does not meet a minimum threshold of acceptability will not be accepted for substantive review.

- "Premarket Notification Refuse to Accept Policy." The purpose of this policy is to establish procedures under which a 510(k) that does not meet a minimum threshold of acceptability will not be accepted for substantive review.

To implement these policies, ODE provided staff training on these procedures for all reviewers and other Center staff. In addition, the POS staff has issued or will be issuing new or revised "boilerplate" letters based on these policies and is in the process of making necessary modifications to our PMA, IDE, and 510(k) procedure manuals. At the end of this fiscal year, ODE Guidance Memoranda ("Blue Book Memos") were being prepared to establish the principles embodied in these issue papers as operating procedures for ODE. The Blue Book memos should issue during FY 94 and will be made available to the public through the Division of Small Manufacturers Assistance.

2. Tracking Regulation for 510(k)s and PMAs

Under Section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices that have been approved under PMAs or cleared for marketing via 510(k)s must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life-supporting devices that are used outside of device user facilities, the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking.

FDA's tracking regulations were published in the *Federal Register* on August 16, 1993, and appear at 21 CFR Part 821. These regulations set out what a manufacturer must do to track a device. In addition, the regulations list examples of permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the *Federal Register* (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

3. PMA/510(k) Reference List Program

On October 26, 1993, FDA published a notice in the Federal Register, 58 F.R. 57614 (Oct. 26, 1993), that describes the Medical Device Reference List program. Although this FR notice was published in FY 94, the reference list program has been in effect since December 1990 for PMAs and April 1992 for 510(k)s. Under this program, when a 510(k), for example, is found to be substantially equivalent (SE), the Document Mail Center checks the "reference list" to determine whether the firm that submitted the 510(k) is on the list. [This list contains the names of firms that have unresolved GMP or other compliance-related problems. It is updated every day and provided to ODE by the Office of Compliance(OC).] If the name of the firm is on the list, that file is sent to OC for review. OC, within 21 days of its receipt of a 510(k), will inform ODE whether to proceed or not with the SE letter. If OC informs ODE that the firm has GMP problems related to that device, ODE issues a hold letter to the firm based on the GMP problems. If OC states that it is alright to proceed, the SE letter is issued. The reference list program for PMAs operates in a similar manner.

4. 510(k) Summaries and 510(k) Statements - Interim Rule

On April 28, 1992, FDA published an interim rule in the Federal Register, 57 F.R. 18063 (April 28, 1992), entitled "Medical Devices: Substantial Equivalence; 510(k) Summaries and Statements; Class III Summaries; Confidentiality of Information." This interim rule was issued to implement provisions of the Safe Medical Devices Act of 1990 (SMDA). The rule prescribes the content and format of the "510(k) Summary" of information respecting safety and effectiveness that is submitted to FDA or the "510(k) Statement" of information respecting safety and effectiveness that is made available by the firm upon request by any person. The interim rule also

implements the requirement that firms that submit a 510(k) for class III devices must also include a "Class III Summary" and a "Class III Certification" that they have conducted a reasonable search of safety and effectiveness data about the device type. In addition, the interim rule amends the medical device regulations governing the confidentiality of certain 510(k)s and their summaries. It also requires that persons who submit a 510(k) certify that the data and information are truthful and accurate and that no material fact has been omitted.

The effective date of the interim rule was stayed on June 1, 1992, and the comment period on the rule was extended for another 60 days. See 57 *Federal Register* 23059 (June 1, 1992). The effect of this action was to postpone only the use of the FDA prescribed format for the 510(k) Summaries and 510(k) Statements. These summaries and statements themselves, as prepared by the manufacturer, must still be submitted because they are required by SMDA. This requirement has been in effect for all 510(k)s originally received on or before April 18, 1991. The effective date of the new final rule, including format requirements, will be 60 days after the date FDA publishes the final rule in the *Federal Register*.

5. 510(k)/GMP Inspection Program

All 510(k)s originally received on or after March 9, 1993 are now subject to the "Interoffice Agreement Regarding ODE/OC/ORA Roles in Supporting a GMP Pre-Clearance Inspection Program for Devices Marketed Through the 510(k) Program." Initially, this program will apply only to 510(k)s for Class III medical devices and, if practicable, will be extended to all 510(k)s.

Under this program, OC is notified upon receipt of each 510(k) classified by the submitter as a Class III medical device. OC checks with the appropriate FDA district office (DO) to determine the regulatory status of the submitter of the 510(k) and all of their manufacturing and sterilization facilities. If there was a recent GMP inspection and there is no unresolved GMP action pending, and there is no other compliance reason why the 510(k) shouldn't be marketed, or, if the firm has not had a recent GMP inspection and the firm is inspected and not out of compliance, OC will notify ODE that an SE letter may be issued if the device is found to be substantially equivalent. The firm will also be notified if the device cannot be found to be substantially equivalent until outstanding compliance issues are settled.

6. Procedures to Handle IDE Overdue Progress Reports.

On July 23, 1993, ODE issued IDE Guidance Memorandum #D93-1, entitled "Overdue IDE Annual Progress Report Procedures" (See Subpart III, A, Guidance for Industry and Reviewers). These new procedures were developed to assure compliance with the IDE regulatory requirement that a sponsor of an IDE application submit an annual progress report. These progress reports are important because they allow FDA to determine whether there are any apparent risks to the subjects enrolled in ongoing clinical investigation throughout its course. Failure to file an annual report may result in withdrawal of approval of the IDE. In support of these procedures, ODE has prepared boilerplate letters to be used in followup, when necessary, during monitoring of IDE applications for annual reports.

7. 510(k) Status Reporting

During this fiscal year, the Center appointed the Center Communications Committee to explore ways in which CDRH could keep industry informed about the status of pending submissions under review with the least interference with the ODE review process. This initiative was undertaken because of the huge number of status calls to ODE from manufacturers about their pending 510(k)s. These calls were dirverting scarce review resources from the primary goal of conducting substantive reviews of the pending submissions and, in turn, was adding further delays to the processing of submissions.

Based in large part upon the report and recommendations of this committee, the Center established a 510(k) reporting system within the Division of Small Manufacturers Assistance. Under this program a manufacturer may obtain status information about its 510(k)s via telefax or mail, including the place a 510(k) holds in the review queue and the average review time of 510(k)s in the reviewing unit.

E. Significant Medical Device Breakthroughs

- On November 2, 1992, Pro Osteon™ Implant 500 Coralline, Hydroxyapatite Bone Void Filler was cleared for marketing. It was the first artificially manufactured material for use as a bone void filler in acute metaphyseal defects of the tibia which are 30 cc. or less in size.

- On November 20, 1992, the Ventricular Assist Device was the first such device to receive FDA approval. It is intended for short term use in patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, allowing the heart to recover adequate mechanical function.

- On February 19, 1993, the CVX-300 Excimer Laser System was approved. Although this is the second coronary laser angioplasty system approved, the indications for use are broader than the first one and include use in totally occluded vessels, ostial lesions and bypass graft lesions.

- On February 25, 1993, two intraocular gases, Sulfur Hexafluoride and Perfluoropropane, both retinal tamponades, were approved. These gases represent two first-of-a-kind devices for the treatment of uncomplicated retinal detachments. These breakthrough devices provide a state-of-the-art modality for retina surgeons.

- On March 2, 1993, the FDA cleared the Accumeter Cholesterol Self-Test, the first in-vitro diagnostic device for home-use to estimate a person's level of cholesterol. This simple test for cholesterol uses a single drop of blood from a fingerstick and takes about 15 minutes to perform. The firm's studies showed the test to be as accurate as cholesterol tests used by doctors and medical laboratories. The user will be able to determine if he or she has an increased cholesterol level and should see a doctor before a serious problem develops.

- On April 30, 1993 and February 11, 1993, respectively, the Multiprogrammable Tachycardia Control System and the Cadence Tiered Therapy Defibrillator were approved for marketing. These are implantable defibrillators which include antitachycardia pacing, low energy cardioversion, high energy defibrillation, and back-up bradycardia support capabilities.

- On May 7, 1993, the Reality™ female condom was approved for marketing. The device, also known as a vaginal pouch, is the first condom-type barrier contraceptive for women. It offers some protection against sexually transmitted diseases (STDs).

- On May 13, 1993, the Guidor™ was cleared for marketing. The Guidor™ is an absorbable material which aids in healing periodontal defects. It is the first absorbable periodontal device of its type cleared for marketing.

- On May 18, 1993, and May 28, 1993, repectively, the Atherectomy System and the Rotablator were approved for marketing. These two percutaneous coronary atherectomy devices represented modifications of previously approved devices in that one aspirated the atherectomy material that was removed and the other debrided the material into fine particles passing through the micro circulation.

- On May 28, 1993, Collagraft™ (Collagen-Hydroxyapatite- Tricalcium Phosphate) Bone Void Filler for Bone Fractures was approved. It is the first collagen-based artificial material for healing acute fractures in long bones, i.e., 30 cc. or longer, in size.

- On May 28, 1993, the Gianturco-Roubin Flex-Stent was approved. This is the first coronary stent approved by FDA and is indicated for chronic placement in a coronary artery to obtain vessel patency in the treatment of acute or threatened closure associated with an interventional procedure.

- On August 26, 1993, the ENDOTAK Transvenous Lead, the first transvenously delivered defibrillator lead was approved. The use of these leads eliminates the need to perform a thoracotomy on patients receiving defibrillators, which lessen operative risks to the patients and reduces the post-operative recovery period.

- On September 29, 1993, the Falope Ring Bard® and Applicator System was approved for marketing. The device is indicated to occlude the fallopian tube lumen to prevent pregnancy. This is the first PMA for a permanent female sterilization product. The PMA was the result of FDA calling for PMAs under the 515(b) process for tubal occlusion devices.

- On September 30, 1993, the Contigen™ Bard® Collagen Implant was approved for marketing. It is indicated for use in the treatment of urinary incontinence due to intrinsic sphincter deficiency (poor or non-functioning bladder outlet mechanisms) that may be helped by a locally injected bulking agent.

IV. OTHER PROGRAM ACTIVITIES

In addition to the review of PMAs, IDEs, and 510(k)s, ODE has been heavily involved in other significant program activities. Several of these are discussed below.

A. Guidance for Industry and Reviewers

Many new guidance documents are developed by ODE and its operating units each year. These documents are designed to promote uniformity and to improve the efficiency, administration, and quality of ODE programs. They also serve as guidance to manufacturers. In addition to dissemination of these guidance documents to appropriate ODE staff members, they have been distributed to the affected industry and made available to interested members of the public. All of these guidance documents are made available by the Division of Small Manufacturers Assistance (HFZ-220) on the Center's electronic bulletin board system, via telefax and in hard copy at - BBS: (301) 594-4802; TELEFAX: (301) 443-8818; MAIL: 5600 Fishers Lane, Rockville, Maryland 20857; or, VOICE: (800) 638-2041.

The following listing of guidance documents includes documents that were issued in FY 92 as well as the current fiscal year because the Office of Device Evaluation did not issue a full annual report for FY 92. Inclusion of those documents in this report will provide a complete record for future reference.

Guidance Documents Issued During Fiscal Year 1992

- **Office of Device Evaluation (ODE)** •

  Nondisclosure of Financially Sensitive Information. On March 5, 1992, ODE issued Blue Book Memorandum I92-1 to clarify ODE's current policy concerning the disclosure or use of financially sensitive information.

  Training for Supervisors. On March 5, 1992, ODE issued Blue Book Memorandum A92-1 to describe ODE's practices to implement Departmental training and development policies for supervisors.

- **Division of Reproductive, Abdominal, Ear, Nose and Throat Devices (DRAERD)** •

  Urological Balloon Dilatation Catheters. On January 24, 1992, DRAERD issued the Draft Guidance for the Content of Premarket Notification for Urological Balloon Dilatation Catheters. The guidance provides information for the manufacturer to ensure that the submission is complete and to establish substantial equivalence.

  Lithotripsy. On February 5, 1992, the DRAERD issued the Draft Guidance for Information on Clinical Safety and Effectiveness for Extracorporeal Shock Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal Calyx and Upper Ureteral) Calculi. The purpose of the

guidance is to outline the requirements for clinical data in a PMA application for an extra-corporeal shock wave lithotripter for the treatment of upper urinary (renal pelvix, renal calyx and upper ureteral) calculi. This includes results from a well-controlled and well-monitored clinical trial with complete safety and effectiveness data and follow-up.

Picture Archiving and Communications Systems. In August 1993, the DRAERD issued the "Draft" Guidance for the Content and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices. The purpose of the "draft" guidance is to provide definitions of PACS and the applicability of the guidance as well as to update the regulatory issues associated with lossy compression (updates Draft Guidance of 2/91).

- **Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)** •

Stentless Aortic Heart Valves. In Ferbruary 1992, DCRND issued the Draft Guidance for In-Vitro and Animal Testing of Stentless Aortic Heart Valves. This document is a new issue that provides pre-clinical testing requirements for stentless heart valves.

TENS 510(k)s. In July 1992, DCRND issued the Draft Guide for TENS 510(k) Content. This is a clarification of the January 1988 guidance document.

Guide for Intracranial Balloon Embolization Studies. DCRND issued this guidance in November 1992. It describes the type of clinical data that is needed for premarket approval applications and for evaluating protocols in IDE applications.

- **Division of General and Restorative Devices (DGRD)** •

Liquid Germicides. On January 31, 1992, DGRD issued "Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Germicides." This guidance specifies the recommended performance tests to be included in 510(k) submissions.

Resorbable Periodontal Barriers. In 1992, DGRD drafted guidance for the preparation of premarket notifications for resorbable periodontal barriers. This draft guidance expands and clarifies the criteria set forth in a policy statement issued in April 1991, regarding the evaluation of absorbable materials for use in treating periodontal defects.

- **Division of Clinical Laboratory Devices (DCLD)** •

Hepatitis A. In November 1991, DCLD issued the "Review Criteria for Assessment of Hepatitis A Virus Total and IgM Antibody In Vitro Diagnostic Devices." This document provides general guidance to manufacturers about the information needed by FDA to approve submissions for in vitro diagnostic devices intended for qualitative or semi-quantitative detection of antibodies to hepatitis A virus in human serum or plasma by radioimmunoassay, enzyme-linked immunoassay, or monoclonal antibody methods.

Hepatitis B. In December 1991, DCLD issued the "Review Criteria for Devices intended for the Detection of Hepatitis B "e" Antigen and Antibody to HBe." This document provides general guidance to manufacturers about the information needed by FDA to approve submissions for in vitro diagnostic devices intended for qualitative detection of HBe antigen, and qualitative or semi-quantitative detection of antibodies to HBe in human serum or plasma using radioimmunoassay, enzyme-linked immunoassay, or monoclonal antibody methods.

Chlamydia. In January 1992, DCLD issued the "Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens." This document provides general guidance to manufacturers about the information needed by FDA to clear submissions for in vitro diagnostic devices intended to detect chlamydiae directly in clinical specimens by immunochemical and other methodologies.

Cyclosporin. In January 1992, DCLD issued "Guidance Criteria for Cyclosporine PMAs." This document provides general guidance to manufacturers about the information needed by FDA to approve submissions for in vitro diagnostic devices intended to quantify cyclosporine in human serum, plasma or whole blood.

Immunohistochemistry Products. In May 1992, DCLD, in conjunction with members of the Immunohistochemistry Quality Assurance Committee of the Biological Stain Commission, issued the "Draft Proposed Format: Package Insert for Immunohistochemistry Products." This document provides specific suggestions to manufacturers about the format and content of package inserts for immunohistochemistry products. It was also published in the November 1992 issue of Biotechnic Histochemistry (the official publication of the Biological Stain Commission).

Parvovirus B19. In May 1992, DCLD issued the "Review Criteria for Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19." This document provides general guidance to manufacturers about the information needed by FDA to approve submissions for in vitro diagnostic devices intended to detect antibodies to B19 in human serum or plasma.

Fecal Occult Blood Tests. In July 1992, DCLD issued the "Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for use in clinical laboratories, physician's offices and/or home use for the qualitative measurement of occult blood in fecal specimens.

IgM Antibodies. In August 1992, DCLD issued the "Review Criteria for In Vitro Diagnostic Devices for Detection of IgM Antibodies to Viral Agents." This document provides general guidance to manufacturers about the information needed by FDA to clear submissions for in vitro diagnostic devices intended for qualitative or semi-quantitative measurement of IgM class antibodies in human serum or plasma by immunochemical and other methods.

Cholesterol In Vitro Diagnostic Devices Using Enzymatic Methodology. In September 1992, DCLD issued the "Review Criteria for Assessment of Cholesterol In Vitro Diagnostic Devices Using Enzymatic Methodology for Clinical Laboratories, Physician's Offices and Home Use." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for quantitative or qualitative measurement of cholesterol by enzymatic methodology using serum, plasma, or whole blood.

Self-monitoring Glucose In Vitro Diagnostic Devices. In September 1992, DCLD issued the "Review Criteria for Assessment of Self-monitoring Glucose In Vitro Diagnostic Devices using Glucose Oxidase Methodology." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for home use for quantitative measurement of glucose in whole blood by the glucose oxidase method.

Estrogen (ER) or Progesterone (PGR) Receptors. In September 1992, DCLD issued the "Draft: Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors in In Vitro Diagnostic Devices." This document provides general guidance to manufacturers about the information needed by FDA to approve submissions for in vitro diagnostic devices intended for the quantitative measurement of estrogen/ progesterone receptors by SBA/DCC and enzyme immunoassay, or qualitative measurement by histochemical receptor binding assays in human tissue specimens.

Immunoglobulins A, G, M, D, and E. In September 1992, DCLD issued the "Draft Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D, and E Immunoglobulin System In Vitro Devices." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for semi-quantitative or quantitative measurement of immunoglobulins in human serum or plasma using immunochemical or other methods.

Guidance Documents Issued During Fiscal Year 1993

- **Office of Device Evaluation (ODE)** -

Telephone Communications Between ODE Staff and Manufacturers. On January 29, 1993, ODE issued Blue Book Memorandum I93-1 for the purpose of establishing efficient and effective written procedures concerning telephone communictions between manufacturers and other third parties and ODE staff members. The primary purpose of these procedures is to enable ODE personnel to use the telephone to request or obtain information necessary for reviewing submissions without compromising the integrity of program activities.

PMA summaries of Safety and Effectiveness and Federal Register Notices of PMA Approvals - Review by the Office of General Cousel (Revised). On June 11, 1993, ODE issued Blu

Book Memorandum P93-1 which sets forth new procedures concerning the review of draft summaries of safety and effectiveness and Federal Register Notices of PMA Approvals by the Office of General Counsel.

Overdue IDE Annual Progress Report Procedures. On July 23, 1993, ODE issued Blue Book Memorandum D93-1 to establish a procedure for the follow-up on sponsor failure to file IDE annual reports.

510(k) Additional Information Procedures. On July 23, 1993, ODE issued Blue Book Memorandum K93-1 which outlines the process and procedures to be followed by review staff to curtail protracted 510(k) reviews.

- **Division of Reproductive, Abdominal, Ear, Nose and Throat Devices (DRAERD)** •

Bone Densitometer. On November 9, 1992, DRAERD issued the Draft Guidance for Review of Bone Densitometer 510(k) Submissions. The guidance provides historical information on bone densitomer, outlines, for the reviewer, a suggested format for preparation of premarket notifications for bone densitometers, including associated devices and identifies for the manufacturer what information is necessary to provide assurance of reasonable safety and efficacy and to establish substantial equivalence.

Falloposcopes. On November 20, 1992, DRAERD issued the "Draft" Premarket Testing Guidelines for Falloposcopes. The purpose of the guideline is to assist in the preparation of a premarket approval application (PMA) for a falloposcope. In particular, the guideline outlines the information needed to fully and clearly describe the device, as well as to characterize all necessary preclinical and clinical testing of the device.

Biopsy Devices. On February 10, 1993, DRAERD issued the Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology. This guidance states that biopsy devices used in gastroenterology and urology are described in FDA regulations under three classifications. The purpose of the guidance is to provide information needed in order to determine substantial equivalence to a device in commercial distribution.

Ureteral Stents. On February 10, 1993, DRAERD issued the Guidance for the Content of Premarket Notifications for Ureteral Stents. The purpose of the guidance is to provide information needed in order to determine substantial equivalence to a device in commercial distribution.

Urodynamic/Uroflowmetry Systems. On February 10, 1993, DRAERD issued the Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems. The purpose of the guidance is to provide information needed in order to determine substantial equivalence to a device in commercial distribution.

Diagnostic Ultrasound. On February 17, 1993, DRAERD issued the Revised 510(k) Diagnostic Ultrasound Guidance for 1993. The purpose of the guidance is to update CDRH's guidance on diagnostic ultrasound 510(k) submissions.

Penile Inflatable Implants. On March 16, 1993, DRAERD issued the Draft Guidance for Preparation of PMA applications for Penile Inflatable Implants. The purpose of the guidance is to assist in the preparation of premarket approval (PMA) applications for penile inflatable implants for the treatment of erectile dysfunction. It may also be useful for the preparation of Investigational Device Exemptions, reclassification petitions, and master files.

Testicular Prosthesis. On March 16, 1993, DRAERD issued the Draft Guidance for Preparation of PMA applications for Testicular Prosthesis. The purpose of the guidance is to assist in the preparation of premarket approval (PMA) applications for testicular prosthesis. It may also be useful for the preparation of Investigational Device Exemptions, reclassification petitions, and master files.

Benign Prostatic Hyperplasia. On March 26, 1993, DRAERD issued the Draft Guidance for the Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH). The purpose of the document is to outline the features of the clinical investigations that FDA would find acceptable in support of investigational device exemptions and premarket approval applications for the treatment of BPH.

Home Uterine Activity Monitors. On March 31, 1993, DRAERD issued Premarket Testing Guidelines for Home Uterine Activity Monitors. The draft guideline is intended to serve as an aid in the preparation of a premarket approval application (PMAs) for a Home Uterine Activity Monitor, as well as an aid to reviewers of such PMAs.

Vasovasotomy Devices. On November 30, 1993, DRAERD issued the DRAFT Guidance Outline - Points to Consider for Clinical Studies for Vasovasotomy Devices. The purpose of the guidance is to provide guidance for clinical trials to establish the safety and effectiveness of vasovasotomy devices.

- **Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)** •

Interventional Cardiology Devices. In May 1993, DCRND issued the Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents. The revised document is a compilation of previous guidance documents for these devices. It contains updated preclinical testing requirements and revised clinical trials requirements, which reflect the recommendations of the Temple report.

Peak Flow Meter Guidance. In April 1993, DCRND issued this guidance to provide information for the appropriate labeling of this device for over-the-counter distribution.

Reviewer Guidance for Respiratory Devices. In February 1993, DCRND issued this guidance to focus on the safe performance of respiratory devices in their electromagnetic environment. The document suggests test procedures and evaluation criteria that may be used to help demonstrate the safety and effectiveness of respiratory devices in their intended environment of use. The guidance incorporates many of the tests and criteria developed for the Draft Standard for the Infant Apnea Monitor.

Guide for Cranial Electrical Stimulation Therapy Device Premarket Approval Content. On August 20, 1993, DCRND issued this guidance. It presents requirements for the type of clinical data to be submitted in support of applications for premarket approval for cranial electrotherapy stimulators.

Replacement Heart Valves. In December 1993, DCRND issued the Draft Replacement Heart Valve Guidance for data to be submitted to FDA in support of applications for premarket approval. This is a revised edition which contains updated pre-clinical and clinical testing requirements which reflect the recommendations of the Temple report.

- **Division of General and Restorative Devices (DGRD)** -

Calcium Phosphate Coating. In November 1992, DGRD made available the calcium phosphate (Ca-P) coating draft guidance for preparation of submissions to FDA for orthopedic and dental endosseous implants. The guidance informs applicants of the critical elements needed (i.e., chemical, crystallographic, physical and mechanical analyses) to adequately characterize their coating.

Suture Labeling. DGRD issued a revised "Suture Labeling Guidance Document" on January 11, 1993, to provide for standardization of suture labeling for the suture materials that had undergone reclassification.

Sterilizers. In March 1993, DGRD issued the "Guidance on Premarket Notification 510(k) Submission for Sterilizers Intended for Use in Health Care Facilities." This guidance outlines the information that must be addressed in 510(k) applications.

Infusion Pumps. In March 1993, DGRD issued a "Guidance on the Content and Format of 510(k)s for Infusion Pumps" describing the information required in submissions for this type of device.

Syringes and Needles. In March 1993, DGRD issued a "Guidance on the Content and Format of 510(k)s for Syringes and Needles" outlining the information necessary to evaluate the device.

Electronic Thermometers. In March 1993, DGRD issued the "Guidance on the Content and Format of 510(k)s for Electronic Thermometers", which specifies the information needed.

Intravenous Catheters. In April 1993, DGRD issued the "Guidance of the Content and Format of 510(k)s for Intravenous Catheters", which explains the information needed to evaluate this type of device.

Testing Orthopedic Implants. The "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement" was issued in April 1993 by DGRD. This document provides mechanical testing methods, methods of data presentation, clinical data requirements, manufacturing details, and required analyses for orthopedic implants with surfaces treated by any manufacturing process that would effect the properties of the bulk material.

Testing Biodegradable Fracture Fixation Implant Devices. In April 1993, DGRD issued the "Guidance Document for Testing Biodegradable Fracture Fixation Implant Devices" which describes test methods and required descriptive analyses, including physical, thermal, mechanical properties, in vitro degradation testing, biocompatibility and clinical data needed for absorbable fracture fixation devices.

Testing Bone Anchor Devices. In April 1993, DGRD issued the "Guidance Document for Testing Bone Anchor Devices" which describes the information necessary concerning the intended use of suture anchor devices, clinical data needed, preclinical testing, including mechanical testing, and failure mechanism identification.

Cemented, Semi-Constrained Total Knee Prostheses. In April 1993, DGRD drafted guidance for the preparation of 510(k) submissions for Cemented, Semi-Constrained Total Knee Prostheses. The administrative and scientific contents required in a 510(k) application for a total knee prosthesis are described in this document. Mechanical testing, device description, and report presentation requirements are also included.

Preparation of 510(k)s for Orthopedic Devices. In April 1993, DGRD drafted a guidance document for the preparation of 510(k) applications for orthopedic devices. This draft guidance contains a description of the administrative, scientific, and regulatory content needed for a complete orthopedic 510(k) application. Additionally, it provides a description of the general requirements for testing and testing reports, as well as a description of the information needed for a review of device labeling, packaging, and sterility.

Automated Endoscope Washers. In August 1993, DGRD issued the "Guidance on Premarket Notification 510(k) Submissions for Automated Endoscope Washers, Washer/ Disinfectors, and Disinfectors Intended for Use in Health Care Facilities." This guidance specifies the performance test information required in submissions of this type.

Surgical Gowns and Drapes. In August 1993, DGRD a "Guidance on Premarket Notification 510(k) Submissions for Surgical Gowns and Surgical Drapes", which specifies the information required in the submission.

Preparation of 510(k)s for Wound Dressing. In September 1993, DGRD drafted guidance for the preparation of a 510(k) for wound dressing. This draft contains a description of the administrative, scientific, and regulatory content needed for complete review.

Preparation of an IDE for Interactive Wound and Burn Dressings. In September 1993, DGRD drafted guidance for the preparation of an investigational device exemption submission for interactive wound and burn dressings, which contains a description of the information required for a complete review.

Intra-Articular Prosthetic Knee Ligament Devices. In February 1993, DGRD issued a "Revised Guidance Document for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Intra-Articular Prosthetic Knee Ligament Devices." This revision was made to incorporate changes in administrative details.

- **Division of Clinical Laboratory Devices (DCLD)** -

Anti-nuclear Antibodies. In October 1992, DCLD issued the "Review Criteria for the Assessment of Anti-nuclear Antibodies (ANA) In Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD), and Enzyme-linked Immunosorbent Assay (ELISA)." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for semi-quantitative or qualitative measurement of ANA in human serum using IFA, IMD or ELISA methods.

Preparation of Premarket Submissions Implementing CLIA. In December 1992, DCLD issued the "Draft FDA Guidance to Manufacturers of In Vitro Analytical Test Systems for Preparation of Premarket Submissions Implementing CLIA" for public comment. This guidance provides information on how FDA will implement its CLIA responsibilities, and what manufacturers should submit to obtain a CLIA Quality Control validation assessment and a CLIA complexity categorization for their device. The comment period ended April 15, 1993. DCLD is reviewing the comments for a future revised draft.

Allergen-Specific Immunoglobulin E. In March 1993, DCLD issued the "Review Criteria for the Assessment of Allergen-Specific Immunoglobulin E (IgE) In Vitro Diagnostic Devices Using Immunological Test Methodologies." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for semi-quantitative or qualitative measurement of Allergen-specific IgE by various immunological test methods such as radioimmunoassay, enzyme immunoassay, chemiluminescent immunoassay, and fluorescent immunoassay.

Nucleic Acid Amplification-Based In Vitro Diagnostic Devices. In June 1993, DCLD issued the "Draft Review Criteria for Nucleic Acid Amplification-Based In Vitro Diagnostic De-

vices for Direct Detection of Infectious Microorganisms." This document provides general guidance to manufacturers about the information needed by FDA to approve or clear submissions for in vitro diagnostic devices intended to detect microorganisms directly from human specimens, using nucleic acid amplification and hybridization methods.

Mycobacteria Ssp. In June 1993, DCLD issued the "Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacteria Ssp." This document provides general guidance to manufacturers about the information needed by FDA to clear in vitro diagnostic devices intended for the qualitative detection of mycobacteria species or group in human specimens by amplification and hybridization techniques.

- **Division of Ophthalmic Devices (DOD)** -

"Multifocal Intraocular Lens Guidance Document." In February 1993, DOD issued this document which contains updates to 3 sections of the June 13, 1990 guidance document: (1) Additional Clinical Substudies, (2) Clinical Study Design, and (3) Data Analysis. The most significant aspects of the document included a requirement of functional visual performance testing (driving simulation study) and fusion/suppression testing (Worth Four Dot Test). In addition, the guidance added statistical information on determining the number of subjects to be enrolled per investigator and a data analysis table format for the presentation of visual acuity and refraction data.

B. Reclassification/Classification of Devices

1. Reclassification of Classified Devices

During FY 93 the following activities occurred concerning the reclassification of medical devices.

- Published a final rule in the Federal Register on January 8, 1993, announcing the reclassification of the Hip-Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis from Class III to Class II. The reclassification was effective on February 8,1993.

- Published a final rule in the Federal Register on May 21, 1993. announcing the reclassification of the Microsurgical Argon Laser for use in rhinology and laryngology from Class III to Class II. The reclassification was effective on June 21, 1993

- Published a proposed rule (515(b)) in the Federal Register on July 6,1993, announcing an opportunity to request a change in classification of the Nonroller-Type Cardiopulmonary Bypass Blood Pump. One reclassification petition to reclassify from Class III to Class II has been received.

- Published a proposed rule (515(b)) in the Federal Register on August 31, 1993, announcing an opportunity to request a change in classification of Cranial Electrotherapy Stimulators. Two reclassification petitions have been received.

- Received a 513(f) petition to reclassify the Nd:YAG Lasers for Iridotomy from Class III to II.

- Received a 513(e) petition to reclassify the Ostomy Bag and Associated Devices from Class I to Class II.

- Received a 513(f) petition to reclassify the Contraceptive Cervical Cap from Class III to Class II.

2. Classification of Unclassified Devices

The Dental Devices Panel recommended the classification of the Glenoid fossa and Mandibular condyle implants, electrical dental anesthesia devices and root apex locators into Class III, at a panel meeting in February, 1993.

C. PMAs for Pre-Amendments Devices (515(b) Regulations)

Pre-Amendments devices classified in Class III, and substantially equivalent post-amendments devices, are not immediately subject to premarket approval under the act. Instead, the act directs FDA to publish regulations, known as "515(b) regulations," calling for PMAs for these devices. A 515(b) regulation may not require the filing of PMAs for a device until 30 months after the device is classified in Class III, or 90 days after the 515(b) regulation is promulgated, whichever is later.

Nearly 150 generic types of devices have been proposed for, or have been finally classified in, class III. Recognizing that FDA could not issue 515(b) regulations simultaneously for all pre-Amendments class III devices, Congress authorized FDA to establish priorities which may be used in applying premarket approval requirements to these devices.

Over the years, 515(b) rules have been promulgated for various high priority devices. During this fiscal year, ODE published 515(b) proposed rules in the *Federal Register* for the following devices:

- Silicone Inflatable Breast Prosthesis, 58 FR 3436 (January 8, 1993)

- Testicular Prosthesis, 58 FR 4116 (January 13, 1993)

- Penile Inflatable Implant, 58 FR 25902 (April 28, 1993)

- Nonroller-Type Cardioplumonary Bypass Blood Pump, 58 FR 36290 (July 6, 1993)

- Cranial Electrotherapy Stimulators, 58 FR 45865 (August 31, 1993)

D. Advisory Panel Activities

ODE held 20 medical device advisory panel meetings during the past year. The meetings covered matters such as implantable defibrillators, testicular and penile implants, home uterine activity monitors, multifocal intraocular lenses, human genetic in vitro diagnostic devices, use of prostate specific antigen as an early detection of prostate cancer, non-thermal effects of diagnostic ultrasound, pedicle screw spinal fixation devices, and TMJ implants. ODE also held its first workshop titled, "Design and Conduct of Clinical Trials for the Evaluation of Cardiovascular Devices." During this past year ODE conducted a meeting of the Advisory Panel Chairpersons (first of its kind) to announce our new management initiatives. As part of the Institute of Medicine's report titled "Food and Drug Administration Advisory Committees," ODE began to implement some of the recommendations identified in the report. ODE continued to conduct formal training sessions for new panel members. Periodic group meetings with the Executive Secretaries were held throughout the year.

E. ODE Integrity Program

1. Guidance Documents

During the last two fiscal years, ODE issued two Integrity Blue Book Memoranda:

- Nondisclosure of Financially Sensitive Information - I92-1, March 5, 1992
- Telephone Communications Between ODE Staff and Manufacturers - I93-1, January 29, 1993

These memoranda are described in Subpart A, above.

2. Data Integrity

During FY 93 it was necessary to request data audits on more than 30 submissions. These directed data audits are in addition to the routine data audits conducted by the Office of Compliance. Some of these requests for directed data audits were based, in part, upon the following factors:

- Internal inconsistencies within the submission that could not be attributed to harmless error, e.g., patient reports compared to summary data;
- Scientifically implausible data on physical attributes of the device or its components, e.g., viscosity ranges, temperature ranges, etc.;
- Contradictory information provided by scientific/clinical researchers, who authored supporting articles or conducted supporting research;
- Data inconsistent with the scientific/professional literature, e.g., the total number of patients treated with a device;

- Information provided by employees of the applicant, e.g., the maintenance of a double set of records; and,

- Information obtained from official documents, e.g., court trial records: complaints, affidavits, etc.

This year saw the issuance of the first letter to a medical device firm by the Center for Devices and Radiological Health pursuant to FDA's "Application Integrity Program" (AIP). The AIP was formerly known as the "Fraud Policy." Under the AIP, the substantive review of all pending and future submissions by the firm to whom the AIP letter is issued is suspended until the firm undertakes an internal audit and implements an acceptable corrective action plan.

3. Program Integrity

During FY 92-93, several ethics issues and conflicts of interest problems arose. These questions involved the receipt by ODE reviewers of unsolicited gifts from the regulated industry. The gifts included bouquets of flowers, pen and pencil sets, books, a dinner, and other small gifts. These gifts were reported to the ODE Integrity Officer who sent warning letters to the offending individuals or firms. In all instances, the gifts were made by "newcomers" to the FDA regulatory arena who were unaware of FDA's stringent conflict of interest rules.

F. Responding to Congressional Inquiries

The nature of congressional activity relative to ODE changed during the past year. In previous years there were relatively few congressional oversight investigations. During the past year, there was a wide array of inquiries directed at the 510(K) backlog. Matters that generated the most interested were autoinhalers, hyperthermia in AIDS, electric wheel chairs, sharps disposal containers, pedicle screws, and disinfectant germicide solutions,

For the first time, a congressman visited ODE in person. Congressman David E. Skaggs of Colorado came to the Piccard building to learn about the 510(k) process. In addition to a briefing, Rep. Skaggs toured the building and visited with ODE staff.

G. Responding to FOI Requests

Under the Freedom of Information (FOI) Act, FDA must respond within 10 days to requests for information contained within agency files, with the exception of trade secret data and confidential commercial information. Requested documents must be "purged" of such privileged information before release. ODE staff received 973 FOI requests during FY 91.

H. Publications

During FY 93, ODE staff authored three abstracts for publication in professional and scientific journals and made 20 presentations at professional and scientific and trade association meetings.

V. SUPPORT ACTIVITIES

A. Staff Training

Extensive training was provided in FY 93 to meet the needs of ODE employees. Input was obtained from ODE staff members, managers, and industry representatives to identify the areas where training was most needed.

ODE staff continue to participate in off-site training to pursue higher level degrees and to obtain training that will enhance their current performance. Furthermore, ODE has been widely represented at professional meetings and workshops throughout the year. Training and registration fees in FY 93 totalled over $278,000, while travel expenditures were almost $269,000 for ODE staff.

Training also included numerous in-house workshops and seminars as well as site visits to manufacturers. The following in-house training programs were developed and instituted this past year.

1. New Reviewer Training

ODE conducted new reviewer training classes, which included an overview of the requirements of the FD&C Act, with emphasis on the 510(k), PMA, and IDE sections of the law, for its scientific reviewers. In these classes, ODE reviewers received information on policies, procedures, practices, and precedent decisions relevant to premarket submission evaluations. This year nine 3-hour training sessions were scheduled for new reviewers. In addition, a PMA Refresher session was held in February.

2. Managers Training

Training for senior staff, as well as branch chiefs, occurred monthly to provide information on management techniques to ODE managers and to discuss current management issues.

3. New Inititatives Training

On July 28 and 30, training was provided for ODE reviewers and managers on several new initiatives: "Refuse to file" for Premarket Approvals (PMAs), "Refuse to Accept" for 510(k)s and IDES, Triage, and Expedited Review. Approximately 225 staff members attended this training.

4. Health Hazard Evaluation Training

On July 14 and 20, health hazard evaluation/risk assessment training sessions were held for physicians, branch chiefs, and associate directors. Due to structural and functional changes that were occurring within the Center, it became apparent that there was a need for consistency in the handling of health hazard evaluations. The training sessions provided a forum for discussion and clarification of various issues related to risk assessments and health hazard evaluations.

5. Workshops and Seminars

- Pathology of Cardiac Diseases. Dr. Ramiah Subramanian of ODE presented five lectures on the pathology of cardiac diseases. The lectures covered normal cardiac anatomy as well as the pathology of congenital heart disease, valvular heart disease, ischemic heart disease, and cardiomyopathy and pericardial diseases. Staff from ODE, OST, and OSB attended the lectures.

- Surgical Lasers A joint meeting between the American Society for Laser Medicine and Surgery and the Office of Device Evaluation was held on March 26 to discuss current and potential future medical applications for lasers. Approximately 50 ODE staff members attended.

- Clinical Validation of Cancer Markers. On April 13, Mario Werner M.D., Professor of Pathology and Laboratory Medicine at George Washington University, presented protocols for clinical studies to validate genomic markers, breast cancer markers, protein and enzyme markers. Attendees received one hour of continuing education credit transferrable to professional societies such as the American Medical Association, the Society for Medical Technology, etc.

- High Self-Esteem and Peak Achievement. This seminar was held on July 1 to address problems encountered by ODE staff who are engaged in stressful, deadline-oriented work and who are undergoing constant change within the organization. Approximately 30 staff members attended the seminar.

6. Teleconferencing Courses

Principles of Epidemiology by Satellite. Nineteen ODE staff members participated in "Principles of Epidemiology," a teleconference training course sponsored by the Centers for Disease Control. CDRH hosted all five satellite broadcasts which took place on March 25, April 8 and 22, and May 6 and 20. The course was designed to empower public health workers to assume a more active role in identifying, prioritizing and addressing health risks in their communities.

7. CDRH Informational Exchange Seminars

- Home Health Care. A seminar was presented on February 9 to provide information that would assist ODE staff in the review of applications for medical devices that are to be used in home health care.

- Human Factors. Information was presented on April 2 to sensitize ODE staff about human factors engineering as it relates to the effects of device design on user performance and its relationship to the safety and effectiveness of these devices.

- Endoscopes. On April 1, the Endoscope Working Group sponsored an educational seminar to offer staff an opportunity to learn about the various applications of endoscopes and,

in some instances, see actual demonstrations of the equipment. At the end of this program, staff from ODE were able to participate in a general discussion period. Forty-five staff members attend.

8. Writing Courses

- Right for the Reader. This was an introductory session for potential writing workshop participants to determine their needs and skill levels. Approximately 50 ODE staff members attended.

- Effective Writing. Effective Writing is an intensive workshop centering on the composition skills needed to produce effective Government letters, memoranda, and reports. It is designed for professionals who have good control of the mechanics of English. Ten staff members completed this course.

9. Scientific Exchange Seminars/Industry Site Visits

Site Visit to Condom Manufacturing Firm. A site visit was made to a condom manufacturing plant on August 24 to observe the condom manufacturing process. This was the first of several planned scientific exchanges with industry through site visits to selected manufacturing firms.

B. Office Automation

With a recent influx of PCs provided through Center funding we were able to provide every person in ODE with a PC. This will eliminate equipment incompatibility and remove the need to convert documents from one word processing format to another.

1. Equipment and Software

The ODE expenditure for equipment and software for FY93 was $191,500. The major types of equipment purchased were:

- 25 AST 386/25
- 52 AST 486/33
- 2 AST 386SX/25 lap top computers
- 9 AST 486/66D computers
- 5 Canon plain paper fax machines (one per ODE division)
- 5 Hewlett Packard 4 laser printers
- 2 Hewlett Packard 4M laser printers
- 9 Hewlett Packard IIIP laser printers
- 1 Talaris 1590 printer

In addition to new equipment, 80% of the AST 286s were upgraded to AST 486s.

2. Tracking Systems

The Office of Information Systems (OIS) continued the conversion of ODE tracking systems to the Oracle database management system with the conversion of the IDE tracking system in March 1992 and the 510(k) system in July 1993. This conversion is part of the OIS goal of an integrated information system implemented on common hardware and with the same database management system.

In July 1993, OIS initiated a requirements analysis for the conversion of the ODE division tracking system to Oracle. It will be converted in FY 94. The PMA tracking system still needs to be converted. Both the division tracking system and the PMA tracking system currently operate under Datatrieve on the VAX.

In August 1993, the division tracking system data became available to DSMA for providing status information to sponsors of device applications. ODE divisions routinely update the tracking system, which enables DSMA to provide accurate information.

3. Document Imaging

The CDRH IMAGE system (optical storage and retrieval system) has seen increased use during FY 93, with 186 ODE users accessing the system. ODE reviewers use the IMAGE system to access completed device applications spanning the time period 1976 to the present. A small percentage of documents reside on IMAGE from the years 1976 - 1986, with much higher percentages from 1987 to the present.

The number of documents on IMAGE increases daily. At the end of FY 91, 3,987 510(k)s were loaded on optical disk. At the end of FY 93, 30,772 510(k)s, 297 PMA originals, and 937 PMA supplements were available for viewing on IMAGE. The number of PMAs available for viewing will increase as pre-1988 PMAs are readied for scanning. Initial scanning of IDEs began at the end of FY 93.

To allow more access to the IMAGE system, OIS provided 10 additional IMAGE view stations to ODE. These view stations were strategically placed within ODE.

To make documents available for viewing early in the review process, ODE has initiated scanning documents on-arrival, starting with PMA originals received after October 1, 1993. On-arrival scanning will expand to cover 510(k)s and IDEs as ODE moves from a paper-bound system to one embracing more electronic storage.

To expand its use in the device application review process, ODE developed and submitted a "readiness plan" for the IMAGE system. The IMAGE readiness plan includes scanning a backlog of PMA documents to IMAGE, converting current PC workstations to IMAGE view stations, and purchasing additional PC/view stations for new hires.

4. Clinical Laboratory Improvement Amendments of 1988 (CLIA)

The Office of Information Systems, working with the Centers for Disease Control and Prevention (CDC), installed a CLIA PC-based application within the Division of Clinical Laboratory Devices. This application uses the Paradox database management software and allows the viewing of complexity determinations from CDC CLIA databases. Future plans call for multiuser simultaneous access to the databases running under Oracle on the VAX.

5. Forms Software

All ODE secretaries and some administrative staff received new AST 486/33 Bravos and the Perform Pro Form Filler software. ODE secretaries will be able to use the forms software to complete a variety of government forms on the PC and print them on an attached laser printer.

6. Networking

ODE continued to connect PCs to its local area network for the immediate purpose of accessing printers and copying boilerplate letters from the lan server. Future network plans include access to the Center Pathworks network on the Vax for sharing documents, and for utilizing databases, CDROMS, and IMAGE.

7. User Support

With 294 computer users in ODE, comprehensive user support was needed. This support included the following: performing equipment maintenance, requesting vendor maintenance, responding to questions on software, connecting equipment to Ethernet and the ODE LAN, installing and moving equipment, installing software, and ordering equipment and software. In addition, user training was provided. Increased user input on automation activities will continue to ensure that ODE managers and reviewers have the tools they need.

VI. STATISTICAL TABLES

[NOTE: Although accurate at the time of publication, the data in the following tables may change slightly in subsequent reports to reflect changes in the regulatory status of submissions or verification of data entry. For example, if an incoming PMA supplement is later converted to an original PMA, changes are made in the appropriate tables. Likewise, some data from earlier reporting periods may have been changed to reflect similar corrections in data entry. These adjustments are not likely to have a significant effect on conclusions based on these data. Percentages of actions are presented in some tables. They may not add up to 100% in all cases due to the rounding off of fractions.]

Table 1. PMA/IDE/510(k) Submissions Received
FY 89 - FY 93

Type of Submission	No. Received				
	FY 89	FY 90	FY 91	FY 92	FY 93
Premarket Approval:					
Original Applications	84	79	75	65	40
Amendments	856	569	680	740	665
Supplements	810	660	593	606	395
Amendments to Supplements	999	1,069	954	897	782
Reports for Orig. Applications	466	479	441	483	442
Reports for Supplements	57	22	15	21	17
Master Files	32	37	42	41	71
PMA Subtotal	3,304	2,915	2,800	2,853	2,412
Investigational Device Exemptions:					
Original Appplications	241	252	213	229	241
Amendments	271	288	283	297	320
Supplements	3,038	3,043	3,647	3,644	3,668
IDE Subtotal	3,557	3,602	4,152	4,170	4,229
Premarket Notification:					
Original Notifications	7,022	5,831	5,770	6,509	6,288
Supplements	3,752	3,531	3,917	4,555	3,940
510(k) Subtotal	10,774	9,362	9,687	11,064	10,228
PMA/IDE/510(k) Total	17,635	15,879	16,639	18,086	16,869

Table 2. Original PMAs
FY 89 - FY 93

Action	FY 89	FY 90	FY 91	FY 92	FY 93
Number received	84	79	75	65	40
PMA Actions:					
Filing Decisions:					
Filed (%)	61(62)	53(52)	52(50)	46(54)	33(62)
Not Filed (%)	37(38)	49(48)	42(40)	28(33)	16(30)
Others(%)	N/A	N/A	10(10)	11(13)	4 (8)
Filing Decision Subtotal	98	102	104	85	53
Review Activities:					
Major Deficiencies	8	33	28	31	21
Minor Deficiencies	8	2	5	5	10
Other[a]	85	67	127	162	171
Review Activities Subtotal	101	102	160	198	202
Review Decisions:					
Approvals(%)	56(49)	47(42)	27(27)	12(24)	24(35)
Approvable(%)	52(45)	45(41)	46(46)	18(37)	23(34)
Not approvable(%)	7 (6)	19(17)	27(27)	15(31)	21(31)
Denials	0 (0)	0 (0)	0 (0)	4 (8)	0 (0)
Approval Decision Subtotal	115	111	100	49	68
Total PMA Actions	314	315	364	332	323
Average review time(days) for approvals:[b]					
FDA	145	228	199	146	328
Non-FDA	17	42	87	40	109
Total	187	283	285	186	437
Average elapsed time(days) for approvals:[c]					
FDA	247	302	335	236	547
Non-FDA	101	113	298	74	252
Total	348	415	633	310	799
Number under review at end of period:[d]					
Active[e]	62	44	49	87	94
(Active and overdue)	(24)	(5)	(2)	(36)	(45)
On hold[f]	52	72	86	77	56
Total	114	116	135	164	150

a/ Includes actions that did not result in an approval/disapproval decision, such as a sponsor directed hold, reclassification of the device and conversion of the PMA to another regulatory category, and official correspondence concerning the abandonment or withdrawal of the PMA, placing the PMA on hold, and other miscellaneous administrative actions.

(Continued on next page.)

Table 2. Original PMAs
FY 89 - FY 93

(Continued from previous page.)

b/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is reset upon receipt of a major amendment. Thus, these average review times may exclude review time that accurred prior to the receipt of a major amendment. The review clock also may be stopped and resumed, but not reset, for approvable letters. Filing and minor deficiency letters have no effect on the clock. This average review time will include all such increments of review that occurred after the receipt of the last major amendment, if any.

c/ The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus, the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

d/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

e/ FDA responsible for processing application.

f/ FDA's processing of applications officially suspended pending receipt of additional information from the applicant.

Table 3. PMA Supplements
FY 89 - FY 93

Action	FY 89	FY 90	FY 91	FY 92	FY 93
Number received	810	660	593	606	395
PMA Supplement Actions:					
Panel Track Filing decisions:[a]					
Filed(%)	21(81)	6(35)	5(38)	4(27)	1 (1)
Not Filed(%)	5(19)	11(65)	8(62)	11(73)	6 (9)
Other(%)	N/A	N/A	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	26	17	13	15	7
Review Activities:[a]					
Major Deficiencies	18	30	14	2	5
Minor Deficiencies	1	0	0	0	0
Other[b]	171	292	251	196	251
Review Activities Subtotal	190	322	265	198	256
Review Decisions:					
Panel track approvals(%)[c]	13 (2)	5 (1)	2 (1)	1 (1)	2 (1)
Nonpanel track approvals(%)	506(76)	695(76)	478(64)	393(62)	352(62)
Approvable(%)	119(18)	138(15)	138(18)	120(18)	91(16)
Not approvable(%)	47 (7)	87 (9)	134(18)	122(19)	124(21)
Approval Decision Subtotal	662	919	752	636	569
Total PMA Supplement Actions	878	1,258	1,030	849	832
Average review time(days) for approvals:[d]					
FDA	109	133	111	113	168
Non-FDA	31	26	32	22	35
Total	140	159	143	135	203
Average elapsed time(days) for approvals:[e]					
FDA	122	146	131	135	213
Non-FDA	41	35	44	32	56
Total	163	180	175	167	269
Number under review at end of period[f]					
Active[g]	364	215	206	341	346
(Active and overdue)	(62)	(7)	(1)	(98)	(173)
On hold[h]	167	120	133	144	119
Total	531	335	339	485	465

a/ Filing, not filing, major, and minor deficiency letters are issued for panel track PMA supplements only. Nonpanel track PMA supplements are automatically filed upon receipt.

Table 3. PMA Supplements
FY 89 - FY 93

(Continued from previous page.)

(Continued on next page.)

b/ Includes actions that did not result in an approval/disapproval decision, such as a sponsor directed hold, reclassification of the device and conversion of the PMA supplement to another regulatory category, and official correspondence concerning the abandonment or withdrawal of the supplement, the status of the supplement as a special (changes being effected) or 30 day submission, and other miscellaneous administrative actions.

c/ Panel track supplements require the full administrative procedures normally associated with original PMAs, i.e., Panel review, preparation of a summary of safety and effectiveness, and publication of a *Federal Register* notice.

d/ Average review times in parentheses are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is reset upon receipt of a major amendment. Thus, these average review times may exclude review time that accurred prior to the receipt of a major amendment. The review clock also may be stopped and resumed, but not reset, for approvable letters. Filing and minor deficiency letters have no effect on the clock. This average review time will include all such increments of review that occurred after the receipt of the last major amendment, if any.

e/ The average elapsed time includes all increments of time a PMA was under review, including all of the increments of time it was under review by FDA and all increments of time it was on hold, during which time it was being worked on by the manufacturer. Thus, the average elapsed time is the average time taken to obtain approval of a PMA from its filing date until it receives final approval.

f/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

g/ FDA responsible for processing application.

h/ FDA's processing of application officially suspended pending receipt of additional information from the applicant.

Table 4. Original IDEs
FY 89 - FY 93

Action	FY 89	FY 90	FY 91	FY 92	FY 93
Number received	241	252	213	229	241
Number of decisions:					
Approved(%)	89(36)	95(38)	72(33)	68(32)	60(24)
Not approved (%)	143(58)	146(59)	141(64)	130(60)	166(67)
Other (%)[a]	13 (5)	7 (3)	7 (3)	17 (8)	22 (9)
Total	245	248	220	215	248
Average FDA review time (days)	29[c]	29	29	30	28
Percent (%) of decisions made within 30 days	100[c]	99	99	97	97
Number under review at end of period[b]	16	20	12	21	14
Number overdue at end of period	0[c]	0	1	0	3

a/ Includes deletions, withdrawals, and other administrative actions not resulting in an approval/disapproval decision.

b/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

c/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no IDEs were logged out and the clock was suspended for purposes of counting the 30 day review period. For IDEs that were in ODE during the closed period and for which the review period exceeded 30 days, up to 18 days were subtracted from the review time to determine average review times and to determine whether the document was overdue. This policy was announced in two letters to submitters of IDEs and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377.

Table 5. IDE Amendments
FY 89 - FY 93

Action	FY 89	FY 90	FY 91	FY 92	FY 93
Amendments received[a]	271	288	283	297	320
Decisions on amendments:					
Approved(%)	127(45)	123(46)	133(46)	127(43)	93(29)
Not approved (%)	78(28)	79(29)	80(28)	92(31)	131(40)
Other (%)[b]	75(27)	68(25)	74(26)	78(26)	100(31)
Total	280	270	287	297	324
Average FDA review time (days)	23[e]	24	23	24	25
Percent (%) of decisions made within 30 days	99[e]	99	99	99	96
Average approval time (Days) for IDEs with amendments:					
FDA time	68	73[f]	71	79	83
Non-FDA time	108	114[f]	118	109	129
Total time[c]	176	187[f]	189	188	212
Amendments under review at end of period[d]	11	29	25	21	16
Amendments overdue at end of period	0[e]	0[e]	0	1	2

a/ Includes only those submission received subsequent to and as a result of the disapproval of an original IDE.

b/ Includes actions that did not result in an approval/disapproval decision, such as withdrawal of the IDE or the amendment by the sponsor, and other administrative actions, e.g., acknowledgement letters concerning the submission of information that did not require independent approval/disapproval and other administrative information, such as a change of address.

c/ The average IDE approval time represents the total time it has taken, on average, for an original IDE that was initially disapproved, to be approved after the submission of amendments to correct deficiencies. The time being measured here covers the period from which the original IDE was received to the final approval of an IDE amendment.

d/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

e/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no IDEs were logged out and the clock was suspended for purposes of counting the 30 day review period. For IDEs that were in ODE during the closed period and for which the review period exceeded 30 days, up to 18 days were subtracted from the review time to determine average review times and to determine whether the document was overdue. This policy was announced in two letters to submitters of IDEs and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377.

f/ An increase in average review times can be expected as the percentage of original IDE approvals rises. This is due to the fact that the "easier" or "better prepared" IDEs, with their shorter review times, are not included with IDE amendments.

Table 6. IDE Supplements
FY 89 - FY 93

Action	FY 89	FY 90	FY 91	FY 92	FY 93
Number received	3,038	3,043	3,647	3,644	3,668
Number of decisions	3,023	2,968	3,705	3,469	3,814
Average FDA review time (days)	22[b]	22	21	23	24
Percent (%) of decisions made within 30 days	99[b]	99	99	99	97
Number under review at end of period[a]	170	245	189	359	213
Number overdue at end of period	0[b]	0	0	4	8

a/ The number under review at the end of a period may not reconcile with the number under review at the end of the previous period (plus receipts less approvals) because of deletions and conversions which are not reflected in the table.

b/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed from June 26 to July 13, for a total of 18 days. During this time, no IDEs were logged out and the clock was suspended for purposes of counting the 30 day review period. For IDEs that were in ODE during the closed period and for which the review period exceeded 30 days, up to 18 days were subtracted from the review time to determine average review times and to determine whether the document was overdue. This policy was announced in two letters to submitters of IDEs and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377.

Table 7. 510(k)s
FY 89 - FY 93

Action	FY 89	FY 90	FY 91	FY 92	FY 93
Number received	7,022	5,831	5,770	6509	6288
Number of decisions:					
Substantially equivalent	4,867	4,748	4,294	3776	4007
Not substantially equivalent	92	117	122	130	135
Other[a]	1,177	1,332	951	956	931
Total	6,136	6,197	5,367	4862	5073
Percent(%) not substantially Equivalent[b]	1.9	2.4	2.8	3.3	3.3
Average review time(days):					
FDA time[c]	66[h]	78	81	102	162
Total time[d]	82[h]	98	102	126	195
Percent(%) of decisions made within 90 days, based on:					
FDA time[e]	99	100[k]	100[k]	94	46
Total time[d]	70[h,j]	57	57	45	20
Number under review at end of period:					
Active[f]	1,270	1,174	1,402	2599	3822
(Active and overdue)	0[h]	0	0	(331)	(1894)
On hold[g]	989	726	889	1352	1335
Total	2,259[j]	1,900	2,291	3951	5157

a/ Includes final administrative actions that did not result in a substantially equivalent/not substantially equivalent decision because the 510(k) or device/product was: withdrawn by the applicant, deleted due to lack of response, a duplicate, not a device, a transitional device, regulated by CBER, a general purpose article, exempted by regulation, and other miscellaneous actions.

b/ Based on "substantially equivalent" and "not substantially equivalent" decisions only.

c/ FDA average review time includes all increments of time FDA reviewed a 510(k) so long as the 510(k) document number did not change, which occurs rarely.

d/ Includes all time from receipt to final decision, i.e., does not exclude time while a submission is on hold pending receipt of additional information.

e/ Considers whether FDA review time remained within 90 days, with FDA's review clock being reset to zero whenever additional information was received (in accordance with 21 *CFR* 807.87(h)).

f/ FDA responsible for processing notification.

g/ FDA's processing of notification officially suspended pending receipt of additional information from the applicant.

h/ In FY 89, ODE moved its offices from Silver Spring to Rockville. During the move the Document Mail Center was closed

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Table 7. 510(k)s
FY 89 - FY 93

(Continued from previous page.)

from June 26 to July 13, for a total of 18 days. During this time, no 510(k)s were logged out and the clock was suspended for our Center was closed from June 26 to July 13, for a total of 18 days. During this time, no 510(k)s were logged out and the clock was suspended for purposes of counting the 90 day review period. In FY 89 and FY 90, for 510(k)s that were in ODE during the closed period and for which the review period exceeded 90 days, up to 18 days were subtracted from the review time to determine the average review time and to determine whether the document was overdue. This policy was announced in two letters to submitters of 510(k)s and in two notices in the *Federal Register* of June 16, 1989, at page 25,705, and, September 8, 1989, at page 37,377.

i/ Based on 10 month data, which is representative of this performance had the Document Mail Center not been closed for 18 days as explained in footnote h, above.

j/ This total includes a large number of submissions for examination gloves submitted immediately before the close of the reporting period.

k/ The percent of decisions made within 90 days based on FDA review time is 100% rounded off from 99.9% in FY 90 and 99.6% in FY 91.

Table 8. Major Submissions Received
FY 83 - FY 93

Type of Submissions	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993
Orig. PMAs	76	65	97	69	81	96	84	79	75	65	40
PMA Supp.	360	435	393	478	700	727	810	660	593	606	395
Orig. IDEs	189	203	204	206	218	268	241	252	213	229	241
IDE Amend.	N/A	N/A	N/A	365	265	316	271	288	283	297	320
IDE Supp.	1,750	3,077	2,457	2,884	2,836	3,391	3,038	3,043	3,647	3,644	3,668
510(k)s	4,477	5,004	5,254	5,063	5,265	5,536	7,022	5,831	5,770	6,509	6,288
Total	6,852	8,784	8,974	8,974	9,365	10,334	11,466	10,153	10,581	11,350	10,952

Table 9. Major Submissions Completed
FY 83 - FY 93

Type of Submissions	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993
Orig. PMAs	46	43	37	72	46	46	56	47	27	12	24
PMA Supp.	327	243	377	477	565	652	519	700	479	394	354
Orig. IDEs	187	198	201	213	224	260	245	248	220	215	248
IDE Amend.	N/A	N/A	361	330	253	327	280	270	287	297	324
IDE Supp.	N/A	N/A	2,190	3,599	2,784	3,405	3,023	2,968	3,705	3,469	3,814
510(k)s	3,162	4,262	5,095	5,359	4,992	5,513	6,136	6,197	5,367	4,862	5,073
Total	3,632	4,746	8,261	10,050	8,864	10,203	10,259	10,430	10,085	9,249	9,837

N/A - Not available.

Appendix A. ODE Staff Roster
Fiscal Year 1993

Office of the Director

Acker, Rita
Alpert, Susan
Anderson, Alan
Breslawec, Halyna
DeMarco, Carl
Gornick, MaryAnn
Grygier, Debbie
Kyper, Charlie
Melvin, Marsha
Phillips, Phillip
Pluhowski, Nancy
Taylor, Elaine
West, Dave

Program Management Office

Abernethy, Scott
Appler, Kathryn
Barnes, Roger
Broughton, Shirley
Chesmore, Kaye
Clingerman, Angie
Cornelius, Beth
Dowtin, Lesa
Franke, Kathy
McGheehan, Robert
Jaeger, Jeffrey
Robins, Lisa
Trammell, Dan
Wedlock, Chuck

Program Operations Staff

Adams, Tonja
Allen, Gene
Alpert, Arnold
Berk, Eugene
Blackwell, Michael
Byington, Tonya
Campbell, Vera
Chissler, Robert
Donoghue, Mary
Eady, Mike
Fisher, Lisa
Hadley, Kaelyn
Huff, William
Jackson, Barbara
Jeffries, Melpomeni
Lewis, Jessica
Lundsten, Kathy
Lyons, Linda
Parker, Mervin
Parkhurst, John
Perticone, Diane
Puglisi, Mike
Robinson, Mary Jo
Rosecrans, Heather
Sheridan, Kate
Shulman, Marjorie
Sterniolo, Mike
Wright, Mark

Division of Clinical Laboratory Devices

Appell, Ray
Aziz, Kaiser
Berko, Retford
Blagmon, Djuana
Brindza, Larry
Bucher, Betty
Chace, Nina
Fugate, Kearby
Gaffey, Claudia
Gutman, Steven
Gonzalez, Augustin
Hackett, Joe
Hanna, Nancy
Hansen, Sharon
Harris, Pam
Hawthorne, C. Ann
Jackson, Damia
Jefferson, Mildred
Johnson, Veronica
Jones, Doris
Lappalainen, Sharon
Magruder, Louise
Maxim, Peter
McClain, Joan
Moore, Debra
Moore, Nancy
Nutter, Cathy
Ohrmundt, Jan
Poole, Freddie
Rahda, Edappallath
Robertson, Karen
Robinowitz, Max

Rooks, Cornelia
Selfon, Nathaline
Shively, Roxanne
Simms, Thomas
Sliva, Clara
Stewart, Willard
Tsakeris, Tom
Vadlamudi, Srikrishna
Wei, Tina
Wellstead, Sybil
Wilson, Theresa
Yoder, Freda

Division of Cardiovascular, Respiratory, and Neurological Devices

Abel, Dorothy
Acharya, Abhijit
Astor, Brad
Bazaral, Mike
Burdick, William
Burte, Francoise
Byrd, Glenn
Callahan, Tom
Carey, Carole
Cheng, Jim
Ciarkowski, Art
Costello, Ann
Curtis, Fran
Dahms, Don
Danielson, Judy
Dillard, Christina
Dillard, Jim
Donelson, Jan
Gantt, Doyle
Glass, John
Gluck, Michael
Hinckley, Stephen
Hoang, Quynh
Hwang, Shang
Jones, Jeff
Justice, Dina
Keely, Lev
Kennell, Lisa
Lemperle, Bette
Letzing, William
Massi, Mark
Mazzaferro, Robert
McCulloch, Diane
Morris, Janine
Moyal, Albert
Munzner, Robert
O'Neill, Carroll
Palmer, Ken
Peters, Kim
Price, Veronica
Reamer, Lynne
Roy, Joydeb
Ryan, Tara
Shiu, Lana
Sapirstein, Wolf
Scopec, Marlene
Shanker, Rhona
Shein, Mitchell
Sliwiak, Joan
Sloan, Chris
Smallwood, Senora
Subramanian, Ramiah
Sutton, William
Teague, Nancy
Terry, Doris
Tran, Ann
Trinh, Hung
Unger, Julie
Wentz, Catherine
Zier, David
Zuckermann, Bram

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Barrett, Suzanna
Basu, Sankar
Benninger, Paul
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Budd, Roger
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Courtney, Mike
Cricenti, Pat
Downs, Kathleen
Einberg, Elmar
Felten, Richard
Gaines, Keissa
Gantenberg, Julie
Glass, Jerilyn
Hlavinka, Louis
Hoard, Renita
Jan, George
Kramer, Mark
Lang, John
Lee, Kevin
Less, Joanne
Levine, Jerome
Lin, Chiu

Mattan, Amalie
McDermott, Ken
McGunagle, Dan
Melkerson, Mark
Miller, Allison
Minear, Diane
Mishra, Nirmal
Niver, Samie
Novack, Jeanne
Novick, Andy
O'Connell, Greg
Ogden, Neil
Price, Rochelle
Rao, Prasad
Rhodes, Stephen
Riegel, Elizabeth
Rosile, Nadine
Saas, Holly
Sands, Barry
Schroeder, Maria
Scott, Pamela
Scott, Walter
Scudiero, Jan
Shire, Sandra
Singleton, Greg
Smith, Gwendolyn
Sternchak, Richard
Stevens, Theodore
Sung, Pei
Thomas, David
Tilton, Paul
Torres-Cabassa, Angel
Tylenda, Carolyn
Ulatowski, Tim
Vinson, Priscilla
Wei, Tina
Weiblinger, Richard
Wilkerson, Paula
Williams, Richard
Wolanski, Nicole
Wolf, Beverly
Wong, Linh
Yahiro, Martin

Division of Ophthalmic Devices

Balham, Rhonda
Batra, Karaam
Beers, Everett
Brogdon, Nancy
Brown, Daniel
Buas, Connie
Calloway, Jan
Calogero, Don
Chen, Tzeng
Cohen, Linda
Coleman, Yvette
Coppola, V. Anne
Falls, Deborah
Felton, Eleanor
Fox, Pat
Gelles, Muriel
Gouge, Susan
Jan, George
Jones, Sue
Kaufman, Daryl
Knight, Emma
Lewis, Debra
Matchette, Stephanie
McCarthy, Denis
Moore, Shirley
Nicholas, Marsha
Pettinato, Mark
Rogers, Donna
Saviola, Jim
Schwartz, Tracey
Shih, Ming
Sloane, Walter
Smith, Myra
Storer, Pat
Thornton-Wilburn, Sara
Ung, Neary
Usher, Wil
Waxler, Morris
Whipple, Dave
Williams, Ann Marie
Yoza, Alice
Zollo, Mary Jo

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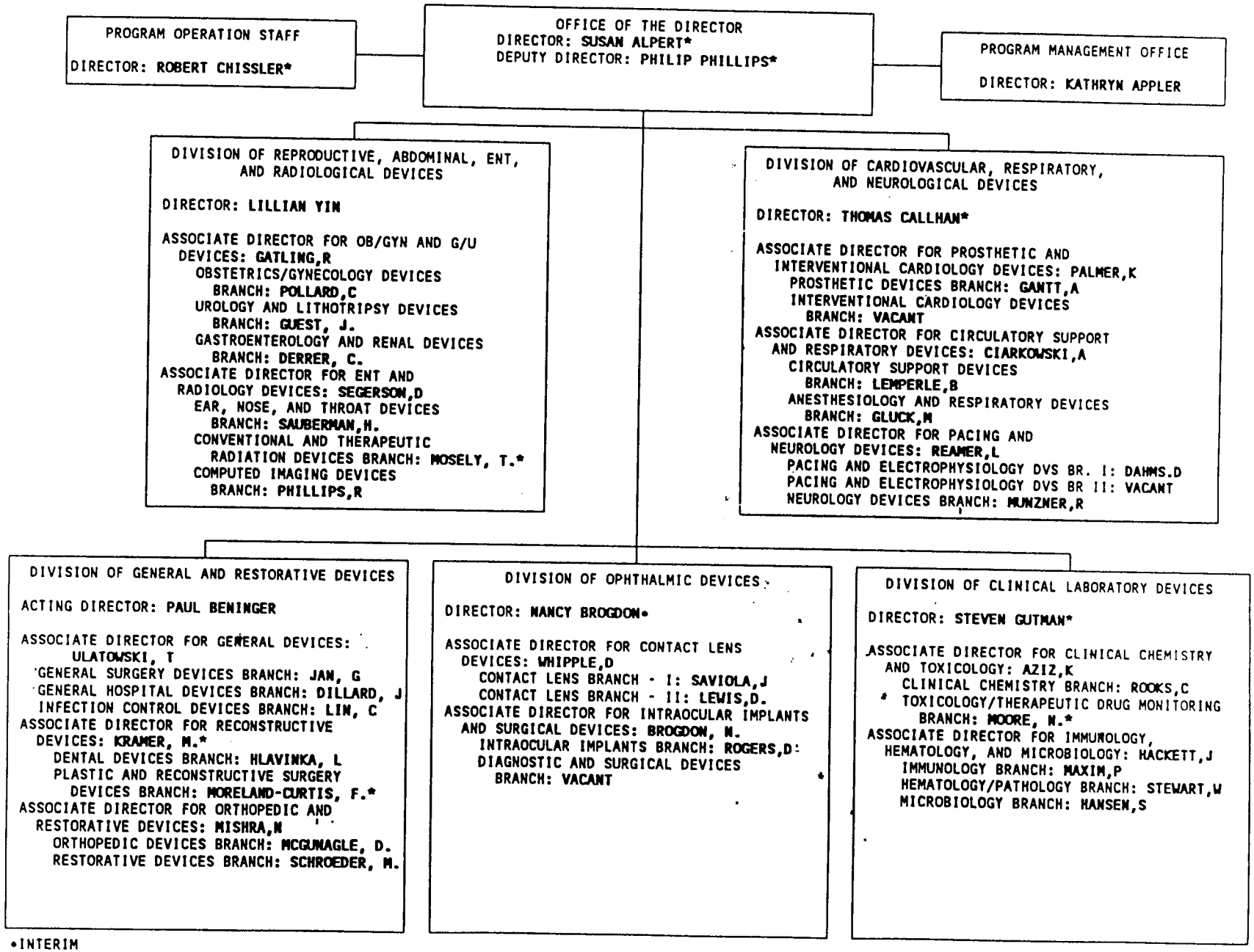
Arnaudo, Joe
Baxley, John
Bradley-Allen, Cheryl
Braver, Christine
Butler, Maureen
Byrd, Laura
Cornelius, Mary Jo
Dart, Linda
Dawisha, Sahar
Daws-Kopp, Kathryn
Derrer, Carolyn
Evans, Cliff
Foster, Felisa
Fredericksen, Jane
Galdi, Adrianne
Gatling, Robert

Geiger, Franklin
Guest, John
Howell, Heather
Jasper, Susan
Kaltovich, Florence
Kammula, Raju
Kastrinakis, Marianna
Kuchinski, Mike
Maloney, William
McCool, Barbara
Miller, Pam
Mills, George
Monohan, John
Mosely, Tom
Neuland, Carolyn
Nimmagadda, Rao
Olvey, Kathleen
Parisian, Suzanne
Perez, Rod
Phillips, Robert
Pollard, Colin
Relacion, Cheryl
Rubendall, Rita
Sauberman, Harry
Scott, Leah
Segerson, Dave
Seiler, Jim
Sharpe, Ellsworth
Shuping, Ralph
St. Pierre, Don
Stuart, Brandi
Tsai, Miin-Rong
Williams, Eugene
Yin, Lillian
Zaremba, Loren

OFFICE OF DEVICE EVALUATION

(UPDATED 10/20/93)



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*ACTING