DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date AUG – 1 1995

From Director, Office of Device Evaluation

Subject Office of Device Evaluation Annual Report for Fiscal Year 1994

To Director
Center for Devices and Radiological Health

Attached is the ODE Annual Report for Fiscal Year 1994. The Preface contains background information and provides an orientation that should be of interest.

On behalf of ODE staff and management, I wish to thank all the CDRH offices for providing support and help during the past year. We look forward to a very productive FY 95.

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

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1994

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 the Office of Information Systems, provided most of the data used in this report. Many staff members within the ODE Review Divisions and Program Management Office also made significant contributions of data and information. The report was edited by the Publications Support Branch, Office of Management Services.

Carl T. DeMarco
Project Director

Table of Contents

PREFACE

During Fiscal Year 1994, the Office of Device Evaluation continued to build on the foundations laid during the previous fiscal year. In addition to stabilizing the device evaluation program, we adopted enhancements in the program areas, improved our organizational structures, added much needed staff, and made significant advances in the performance of submission evaluations.

In the organization and management areas, we conducted a major hiring effort that resulted in the addition of 104 new employees, expanded our new employee training and the training of our executive secretaries and panel members, converted most of our databases to a new database management system, and moved our offices to new facilities.

In the program area, we issued 58 guidance documents to assist ODE review staff and manufacturers in the efficient preparation and review of submissions. Several of these guidance documents have broad applicability and the potential to yield high dividends in speeding up the review process. These broad guidance documents included the "Triage" Review Procedures, PMA/510(k) Expedited Review, Refuse to Accept/File Procedures for PMAs, IDEs, and 510(k)s, the PMA Closure memorandum, and the 510(k) Sign-Off Procedures. In addition, we proposed the exemption of 164 Class I devices from premarket notification, and developed a strategy for the review of the regulatory status of preamendments Class III devices.

In terms of program performance, we completed the review of a record number of 510(k)s, reduced the total 510(k)s under review at the end of the fiscal year, and dramatically reduced the number of 510(k)s that were active and overdue. There was a significant increase in the number of PMA actions and PMA supplement approval decisions. We reduced the number of PMAs and PMA supplements under review at the end of the fiscal year and there was also a significant decrease in the number of PMAs and PMA supplements under review and overdue at the end of the year.

I want to thank the ODE staff for persevering during these times of change. Without their cooperation and hard work, the progress made during FY 94 would not have been possible. Keep up the Good work! I also appreciate the support and assistance of Center management and the other CDRH Offices during FY 94.

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

EXECUTIVE SUMMARY
OFFICE OF DEVICE EVALUATION ANNUAL REPORT
FISCAL YEAR 1994

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. Following are the highlights of ODE activities for Fiscal Year 1994 (FY 94). These are explained more fully in the body of the report.

Workload

During FY 94 ODE received 16,905 total submissions. This represents a an increase of 36 from the total submissions received in FY 93. The FY 94 total receipts represents the second largest number of total submissions ever received during one fiscal year. This year's total is in line with our experience in earlier fiscal years with the exception of FY 92 when an exceptional number of submissions totaled 18,086. The trend is different for the number of major submissions: PMAs, PMA supplements, IDEs, IDE amendments, IDE supplements, and 510(k)s. We received a total of 10,293 major submissions during FY 94, which resents the second consecutive year in which there has been a decrease in the number of major submissions.

Importantly, on the output side, ODE completed the review of 11,045 major submissions, an increase of 1,208 from the 9,837 major submissions reviewed during FY 93. This represents a two-year trend of increases in the number of major submissions completed.

Resources

ODE began FY 94 with 291 employees on board and ended the year with 368 employees on board. During this fiscal year, there was a ceiling of 368 FTEs within ODE. The total FTEs actually used during this fiscal year was 328, an increase of 55 over the number burned in FY 93.

In FY 94, ODE lost 27 employees (18 scientific reviewers and 9 support staff) through resignation or retirement. This attrition was offset by the addition of 104 new employees: 93 scientific reviewers, 8 of whom are medical officers, and 11 support staff.

In late FY 94, ODE began its move into new offices. Over the weekend of June 10-12, 1994, the Division of Clinical Laboratory Devices moved from 1390 Piccard Drive to 2098 Gaither Road, Rockville, Maryland 20850. Immediately after the close of the fiscal year, the remainder of ODE moved from the same location to 9200 Corporate Boulevard, Rockville, Maryland 20850. The latter move was postponed until after the close of the fiscal year in order to minimize the impact of the move on office scheduling of panel meetings and end-of-year processing of applications.

Premarket Approval

During this fiscal year, we received 43 original PMAs, three more than the number received in FY 93. The total number of 354 PMA actions, which includes 63 filing decisions, 225 review activity determinations, and 66 approval decisions, rose 31 from 323 last fiscal year. This rise breaks a two year trend of declining PMA actions.

Twenty six PMAs received final approval, two more than the number of approvals in FY 93. Another 22 original PMAs were found to be approvable. The number of PMAs that were found to be not approvable dropped from 21 last year to 18 and there were no denials issued during FY 94. In total, the number of PMA decisions remained stable from 68 last year to 66 for this fiscal year.

Average FDA review time for original PMAs increased from 328 days in FY 93 to 374 days during FY 94. Non-FDA review time dropped from 109 days in FY 92 to 78 days this fiscal year. On balance, total review time increased somewhat from 437 days last year to 452 days in FY 94.

The total number of PMAs under review at the end of the fiscal year dropped for the second year in a row, from 150 to 139. The active PMAs under review at the end of this fiscal year also went down to 67 from 94 last year, while those on hold increased from last year, from 56 to 72. Fortunately, the number of PMAs that were active and overdue decreased from 45 last year to 22 at the end of FY 94.

During FY 94, the number of supplements received continued a downward trend from last year's 395 to 372. The total number of PMA supplement actions, which includes five panel track filing decisions, 220 review activity determinations, and 584 review decisions, also dropped slightly to 809 from last year's 832 total actions.

The FDA average review time for PMA supplements went up from 168 days in FY 93 to 253 days this year and total review time averaged 295 days during FY 94, an increase of 92 days over the 203 days of total review time averaged during last fiscal year. In addition to the rise in FDA average review time, the non-FDA review time increased from 35 days in FY 93 to 42 days in FY 94. Average elapsed time also jumped from 269 days in FY 93 to 371 days this year, due primarily to the increase in FDA elapsed time from 213 to 301 over the same period of time. Non-FDA elapsed time also rose from 56 to 70 days in FY 94.

The 376 total number of PMA supplements under review at the end of this year represents a significant reduction from last year's 465 and is comparable to the pre-FY 92-93 totals. The number of PMA supplements that were active and overdue also decreased from 173 at the end of the last fiscal year to 110 at the end of this year. The number of active supplements was further reduced to 243 from 346 last year but the number of supplements on hold rose slightly from 119 to 133 at the end of FY 94.

Investigational Devices

We received 171 original IDEs during FY 94, a significant drop from the 241 received in FY 93. The same holds true for IDE decisions: the 174 decisions made on original IDEs during FY 94 was down

from 248 last year. The average FDA review time for original IDEs stayed essentially constant at 29 days in FY 94 as compared to 28 days last year. During FY 94, 95 percent of all original IDE decisions were completed within 30 days, down from 97 percent in FY 93. The number of IDEs under review at the end of the fiscal year dropped for the second year in a row, from 14 last year to 11 at the end of this fiscal year. There were no IDEs overdue at the end of the year.

Premarket Notification (510(k))

During this reporting period, ODE received 6,434 original 510(k)s and 4,571 510(k) supplements. Original and supplemental 510(k)s totaled 11,005 submissions, an increase of 777 from the 10,228 received in FY 93. The 7,135 decisions rendered on original 510(k)s during FY 94 is an increase of 2,062 (a 41% increase) over FY 93 and represents an all-time record number of 510(k) reviews.

The total average review time rose from 195 days in FY 93 to 216 days for FY 94 and the FDA review time went up to 184 days from 162 days in FY 93. 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, the impact of the "reference list" program and the "Class III 510(k)/GMP" inspection program. The latter two programs became effective during FY 92 and FY 93 and were discussed in the FY 93 Annual Report, Subpart D.

For the first time, the FY 94 Annual Report contains median review times for 510(k)s. These data appear in Part VI Statistical Tables, Table 7. For FY 94, 50 percent of 510(k)s were completed in 134 FDA review days as compared to 144 days in FY 93. This is the first time the median review time has come down since FY 90. All 510(k)s in the 90th percentile were completed in 396 FDA review days. The median review time based on total time was 155 days and 472 days for the 90th percentile. This modal information based on total review times is a better reflection of what is happening at the present time and should be more useful than average review times 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.

There were 4,374 510(k)s pending at the end of this fiscal year, which represents a significant decrease from the 5,157 510(k)s that represented last year's end-of-year inventory. The number on hold, however, rose from 1,335 at the end of FY 93 to 1,960 at the end of this year. At the end of this reporting period, there were only 460 510(k)s that were active and overdue, down from 1,894 in FY 93, a decrease of 76 percent.

Guidance for Industry and Reviewers

The following list of 58 guidance documents includes documents that were issued in FY 94 by the Office of Device Evaluation and its review divisions. This represents an increase of 15 over the 43 guidance documents issued during the past fiscal year.

Guidance Documents Issued During Fiscal Year 1994

- Documentation and Resolution of Differences of Opinions on Product Evaluations.
- PMA Refuse to File Procedure.
- 510(k) Refuse to Accept Procedure.
- IDE Refuse to Accept Procedure.
- 510(k) Sign-Off Procedures.
- PMA/510(k) Triage Review Procedures.
- PMA/510(k) Expedited Review.
- Premarket Approval Application (PMA) Closure.
- Biocompatibility Requirements for Long-term Neurological Implants.
- Intra-Aortic Balloon Catheters.
- Replacement Heart Valves.
- Autotransfusion Components/Systems.
- Cranial Electrotherapy Stimulators.
- Cortical Electrode.
- Coronary and Cerebrovascular Guidewire.
- Cranial Perforator.
- Biofeedback.
- Neural Endoscope.
- TENS 510(k)s.
- Galvanic Skin Response Measurement Devices.
- Interventional Cardiology Devices.
- Nebulizers, Metered Dose Inhalers, Spacers, and Actuators.
- Premarket Notification Submissions.
- Face Masks and Shields for CPR.
- Peak Flow Meters.
- Rechargeable Battery.
- Ambulatory Electrocardiograph.
- External Cardioverters and Defibrillators.
- Thyroid Autoantibodies.
- Mycobacterium tuberculosis (Addendum).
- Nucleic Acid Amplification/Infectious Microorganisms.
- Alpha-fetoprotein.
- Cervical Cytology.
- Immunohistochemistry Products.
- 510(k) Data.
- Electrosurgical Devices.
- Saline-Filled Silicone Breast Implants.
- Orthopedic Device 510(k)s.
- Sharps Injury Prevention Feature Guidance.
- Orthopedic Implant Test Data.
- Arthroscope 510(k)s.
- Temporomandibular Joint Implants.

- Labeling Wheelchairs/Scooters for EMI.
- 510(k) Guidance for Class II Contact Lenses.
- Labeling for Class III Contact Lenses.
- Picture Archiving and Communications Systems (PACS).
- Vasovasotomy.
- Latex Condoms.
- Hemodialyzer Reuse Labeling.
- Insufflators and Other Related Instrumentation.
- Simplified Radiology Devices.
- Revision of Diagnostic Ultrasound (4/14/94).
- Revision of Diagnostic Ultrasound (4/15/95).
- Urine Drainage Bags.
- Testing Guidance for Non-Latex Condoms.
- Revision of Urodynamic/Uroflowmetry Systems.
- Conventional and Antimicrobial Foley Catheters.
- Checklist for Sterile Lubricating Jelly.

Reclassification/Classification of Devices

During the year, we down-classified the Automated Heparin Analyzer from class III to class II and proposed the exemption of 164 Class I devices from premarket notification. In addition, two advisory panels recommended the reclassification of the Nd:YAG laser for iridotomy and the infant radiant warmer from Class III to Class II.

Classification of Unclassified Devices

On May 6, 1994, FDA published a notice of availability of the Preamendments Class III Devices Strategy Document in the *Federal Register*. The strategy document sets forth the agency's strategy for implementing section 515(i) of the Safe Medical Devices Act of 1990 (SMDA) which requires FDA to review the classification of premendments Class III (premarket approval) devices and either reclassify the devices into class I (general controls) or class II (special controls) or retain them in class III.

In addition, the following classification recomendations were made:

- The Dental Panel, on June 29, 1994, recommended the classification of some bone-filling and bone-augmentation devices into class II and some into class III.

- The Orthopedic Device Panel, on July 22, 1994, recommended the classification of pedicle screws for degenerative spondylolisthesis and trauma in class II.

- The Radiology Devices Panel, on August 29, 1994, recommended the following classifications of picture archiving and communication devices (PACS): 3 devices into class II and 2 into class I exempt.

Call for PMAs for Pre-Amendments Devices

During this fiscal year as part of the implementation of the Preamendments Class III Strategy document, many proposed or final rules were drafted and will be published in the Federal Register during the next fiscal year. The final rules dealt with testicular prostheses and cranial electrotherapy stimulators. The proposed rules cover the OTC denture cushion pad, the OTC denture repair kit, the endodontic heat sterilizer, and the implanted mechanical/hydraulic urinary contingence device.

Advisory Panel Activities

ODE held 23 panel meetings during FY 94 involving 24 meeting days. Each panel met at least once and some panels held several meetings. There were 13 formal training sessions held for new panel members. For career enhancement, ODE opened up the Executive Secretary function to new individuals with the skills and enthusiasm to do the job. Other advisory panel issues dealt with during FY 94 included: diversity of panel membership; the interactive review process; training for executive secretaries; and implementation of the IOM report on FDA advisory committees.

ODE also implemented a toll-free telephone bulletin board to provide information about FDA advisory committees. This will be a particularly useful source for up-to-date information about FDA advisory panels, especially for members of the public who do not have access to the *Federal Register*.

ODE Integrity Program

During FY 94, 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 internal inconsistencies within the submission, scientifically implausible data, contradictory information provided by scientific/clinical researchers, data inconsistent with the scientific/professional literature, information provided by employees of the applicant, and information obtained from legal documents.

This year saw the issuance of four letters to medical device firms 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 AIP, the substantive review of all pending and future submissions by firms to whom AIP letters were issued is suspended until the firms undertake an internal audit and implement an acceptable corrective action plan.

During FY 94, more than 30 ethics issues and conflicts-of-interest problems arose. Several of these questions involved claims by manufacturers that they were not receiving fair or equal treatment during the review process. Other questions arose concerning the receipt by ODE staff of free training, travel expenses, meals, and other things of value from manufacturers. Some questions involved the acceptance of faculty appointments and participation in professional associations.

Freedom of Information Requests and Congressional Inquiries

ODE received 932 Freedom of Information requests and 68 Congressional inquiries during FY 94.

Publications

During FY 94, ODE staff authored three abstracts and four articles for publication in professional and scientific journals and made nine major presentations at professional, scientific and trade association meetings.

Program Management and Support

Extensive training continued to be a vital part of ODE's support activities in FY 94. Training included both in-house and off-site activities and took the form of workshops, seminars, and informational exchange seminars, as well as structured courses at accredited educational institutions. We conducted new reviewer training in conjunction with the CDRH Staff Colloege.

In spite of the rapid increase in staff during FY 94, ODE managed to provide computer equipment to all new ODE employees and to significantly upgrade its existing base of equipment. The use of the IMAGE system by ODE reviewers increased and they had access to an ever increasing number of documents. Progress continued in the conversion of ODE tracking systems to Oracle. The Division of Small Manufacturers Assistance (DSMA), located within the Center's Office of Health and Industry Programs, again used the data from ODE tracking systems to provide status information to sponsors of device applications. FY 94 proved to be a year of significant expenditures for equipment and software to enable reviewers to perform necessary review activities.

ANNUAL REPORT
OFFICE OF DEVICE EVALUATION
FISCAL YEAR 1994

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 1994 (FY 94), October 1, 1993 through September 30, 1994. Part II below discusses the ODE workload and resources available, while Part III examines the performance and activities of the premarket approval, investigational device exemption, and premarket notification programs. Part III also contains comparative performance and trend analyses from previous fiscal years. Part IV covers procedural and policy issues and guidance documents and other management activities 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 94.

II. OVERALL WORKLOAD AND RESOURCES

A. Workload

During FY 94 ODE received a total of 16,905 submissions, 36 more submissions than the number of submissions received in FY 93. The FY 94 total represents the second largest total number of submissions ever received during one fiscal year although it's in line with our experience in earlier fiscal years, with the exception of FY 92, when an exceptional number of submissions totaled 18,086.

The number of major submissions -- PMAs, PMA supplements, IDEs, IDE amendments, IDE supplements, and 510(k)s -- decreased in FY 94. We received a total of 10,293 major submissions, a decrease of 659 from the number of major submissions received in FY 93. This represents the second consecutive year in which there has been a decrease in the number of major submissions.

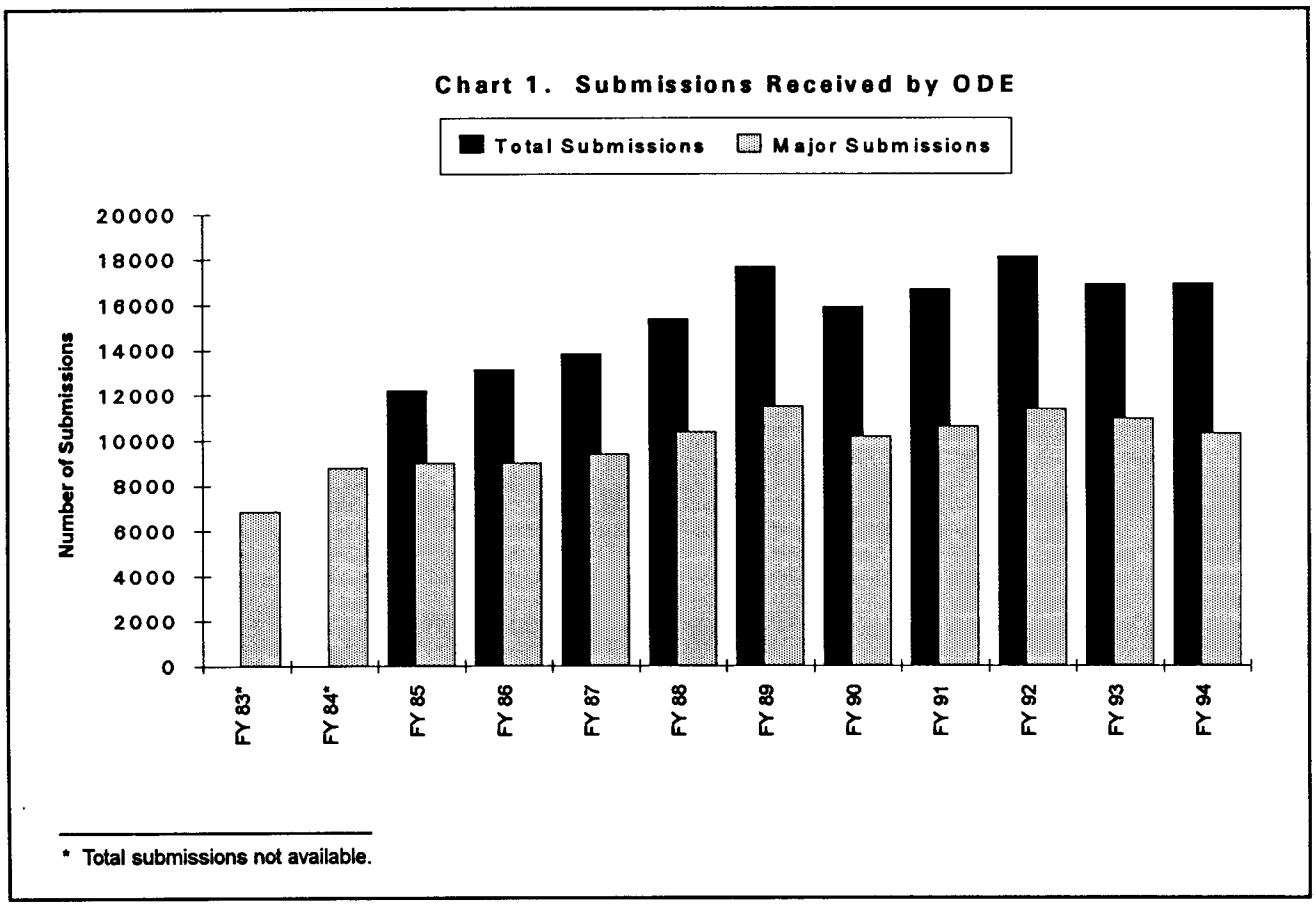
On the output side, ODE completed the processing of 11,045 major submissions, an increase of 1,208 from the 9,837 major submissions reviewed during FY 93. This represents a two-year trend of increases in the number of major submissions reviewed. In terms of output per reviewer, FY 94 is only the third time since FY 83 in which the number of major submissions reviewed per FTE has exceeded the number of submissions received per FTE.

This recent increase in productivity is related in large part to program factors which have increased the efficiency of the review process and refined the processing of submissions. Many of these "management initiatives" were begun in FY 93 and are discussed in the FY 93 Annual Report. They include the "Triage" policy, expedited review, and the "refuse to accept/file" policy for PMAs, IDEs, and 510(k)s. We believe all of these activities have had a positive impact on ODE staff productivity.

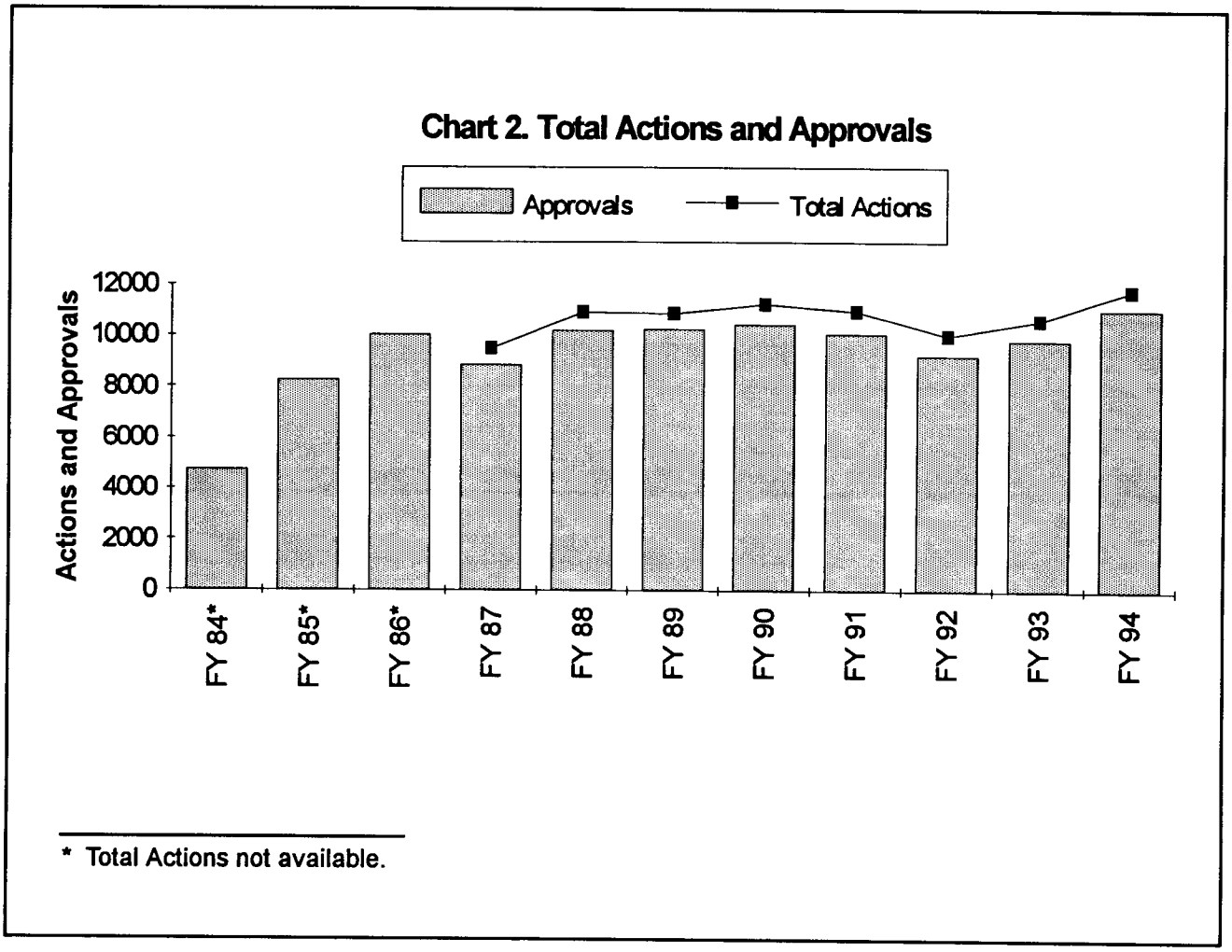
B. Resources

During FY 94, ODE ended the year with 368 employees on board, an increase of 77 from the 291 at the end of last year. During the year, ODE lost 27 employees (18 scientific reviewers and 9 support staff) through resignation or retirement. This attrition was offset by the addition of 104 new employees (93 scientific reviewers, 8 of whom are medical officers, and 11 support staff).

The number of staff on board at the end of the fiscal year does not equal the number of full time staff available throughout the fiscal year in ODE. The ODE staff available throughout the year is represented by the number of full-time equivalents (FTEs) actually used during the year. The number of FTEs available to the program during the year are authorized through the budget process, which established an FTE ceiling of 368 FTEs for ODE. Because hirings were taking

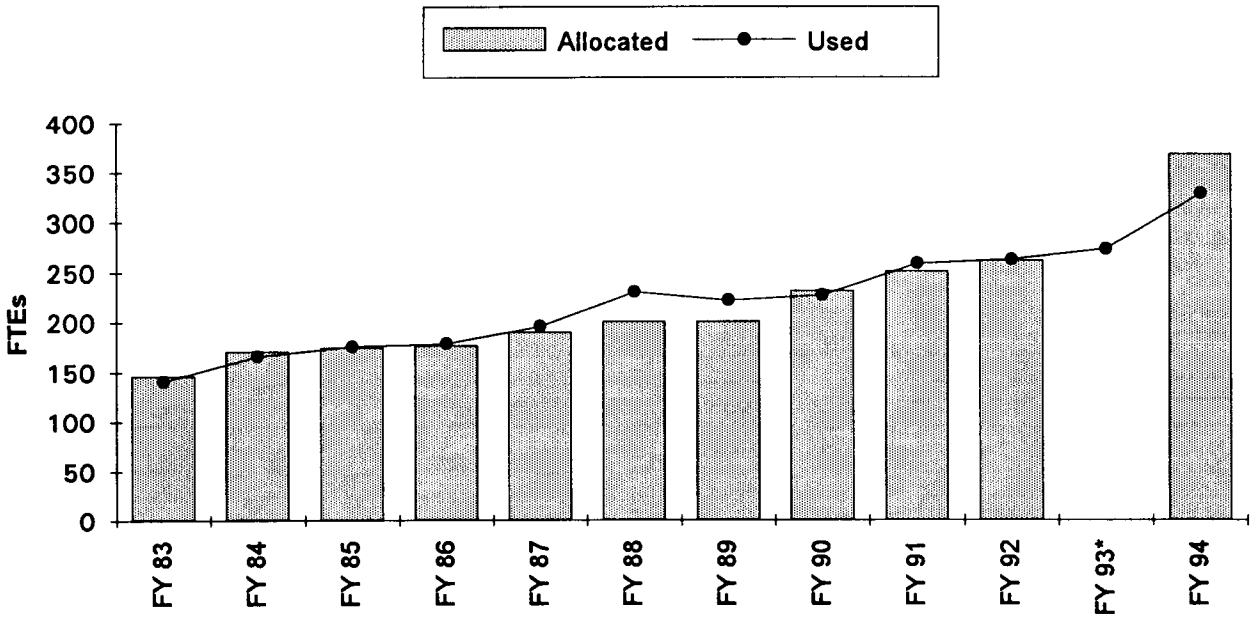


place throughout the year, the actual FTEs used during this fiscal year were only 328, 40 less than the ceiling but an increase of 55 over the number of FTEs used in FY 93. FY 94 is only the second fiscal year since FY 84 in which ODE used fewer FTEs than the number of FTEs allocated.



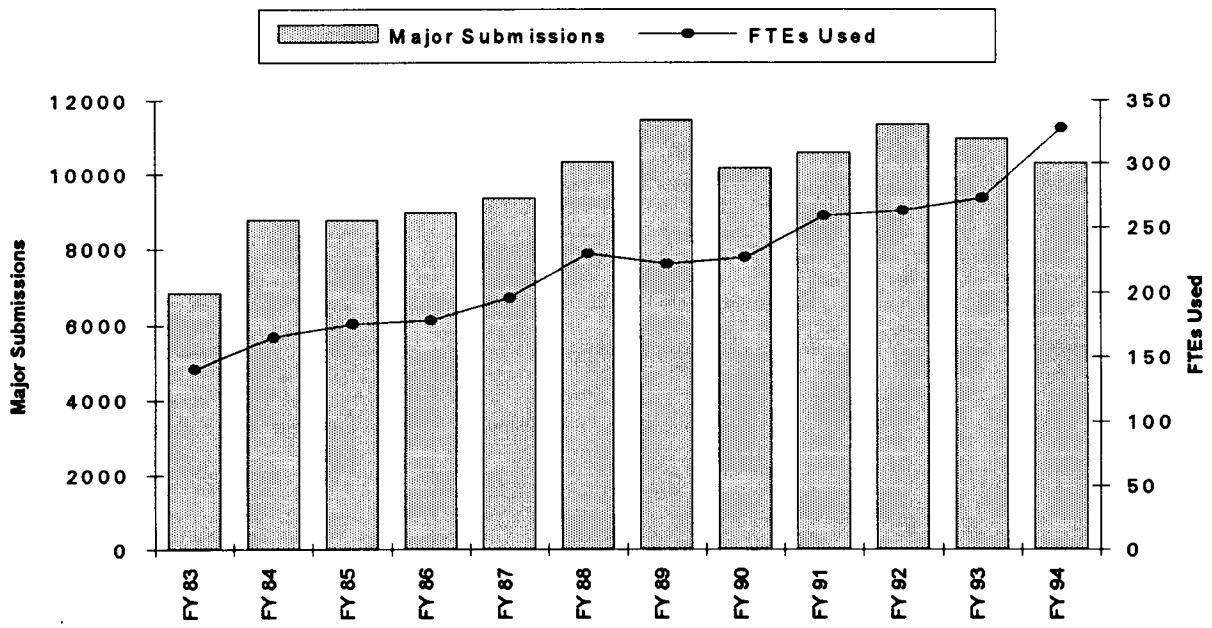
In FY 94 ODE moved into new offices. During the weekend of June 10-12, 1994, the Division of Clinical Laboratory Devices moved from 1390 Piccard Drive to 2098 Gaither Road, Rockville, Maryland 20850. Immediately after the close of the fiscal year, the remainder of ODE moved from the same location to 9200 Corporate Boulevard, Rockville, Maryland 20850. This latter move was postponed until the close of the fiscal year in order to minimize the impact of the move on the end-of-year processing of applications.

Chart 3. ODE Full Time Equivalents



* There was no FTE allocation for FY 93

Chart 4. Major Submissions vs. FTEs Used



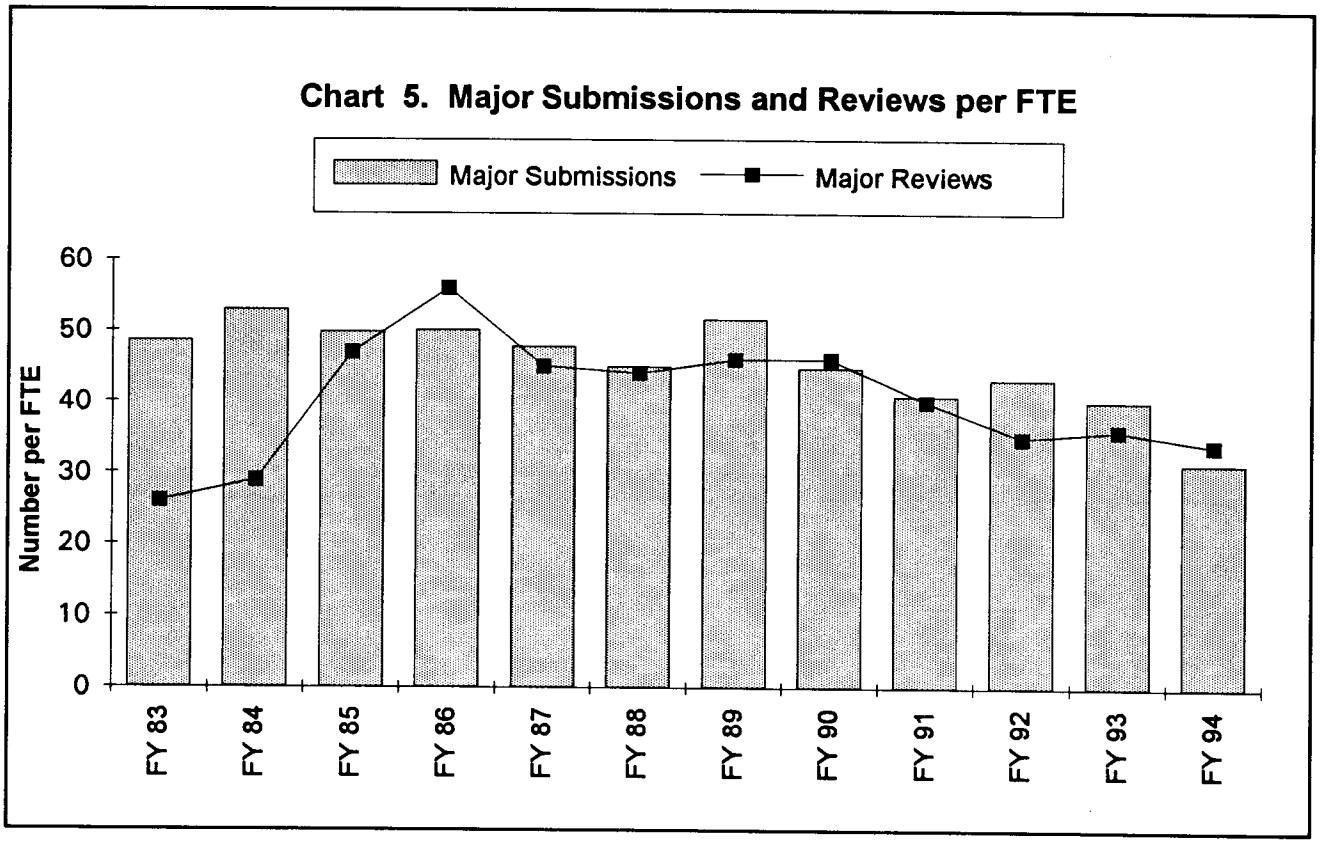


Chart 5. Major Submissions and Reviews per FTE
Major Submissions
Major Reviews
Number per FTE
60
50
40
30
20
10
0
FY 83
FY 84
FY 85
FY 86
FY 87
FY 88
FY 89
FY 90
FY 91
FY 92
FY 93
FY 94

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, and Premarket Notification (510(k)). Subpart D discusses a number of program and policy initiatives 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 or approved 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. Data comparing the current fiscal year to previous fiscal years are displayed graphically throughout the report.

Prior to enactment of the 1986 PMA regulation, 21 CFR 814, PMA review times were calculated in accordance with practices in effect at that time. These review times are referred to as "elapsed time". The PMA regulation's new procedures necessitated a new method for calculation of PMA review times. Time calculated under the PMA regulation is termed "review time". After the enactment of this regulation, ODE continued to report both of these review times for purposes of continuity and to provide a basis for comparison. This dual reporting of review times has been maintained for over five years and the annual report now contains a sufficient number of reporting periods for "review time" under the PMA regulation to provide an historical basis for comparison. Therefore, this annual report will be the last one in which "elapsed time" is reported.

Chart 6. Annual PMA Receipts and Actions

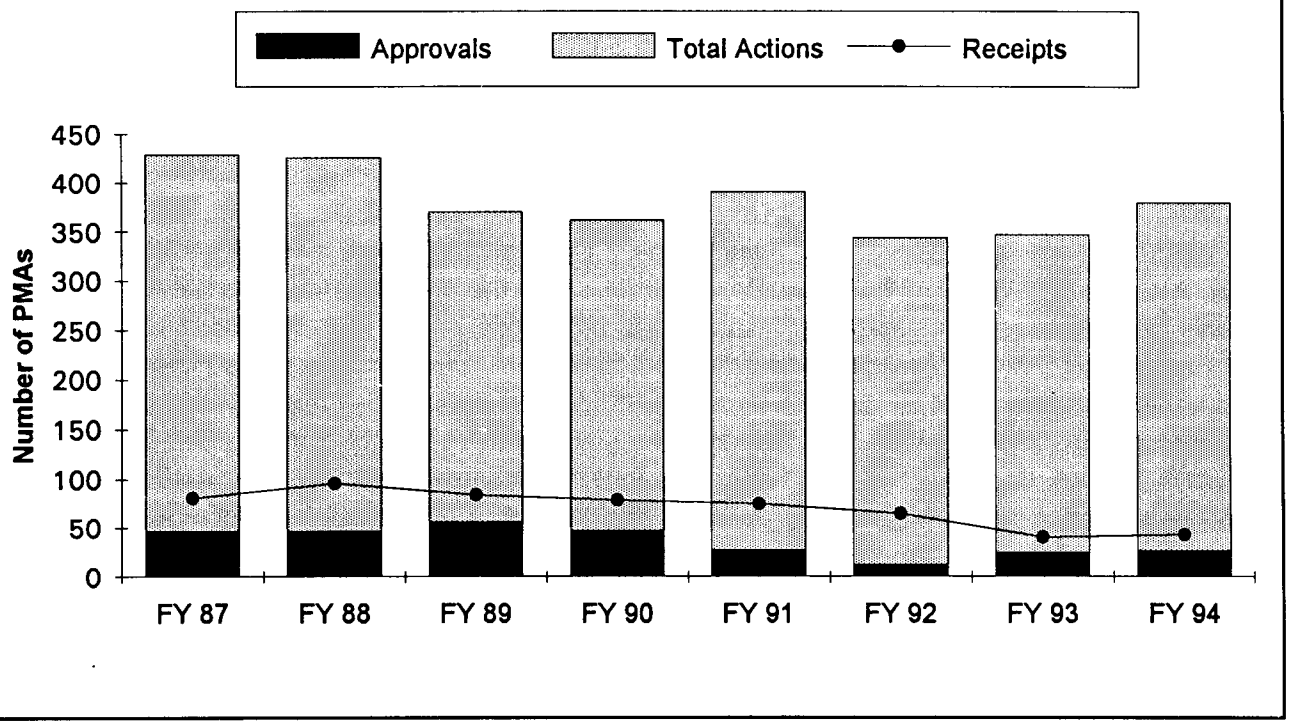
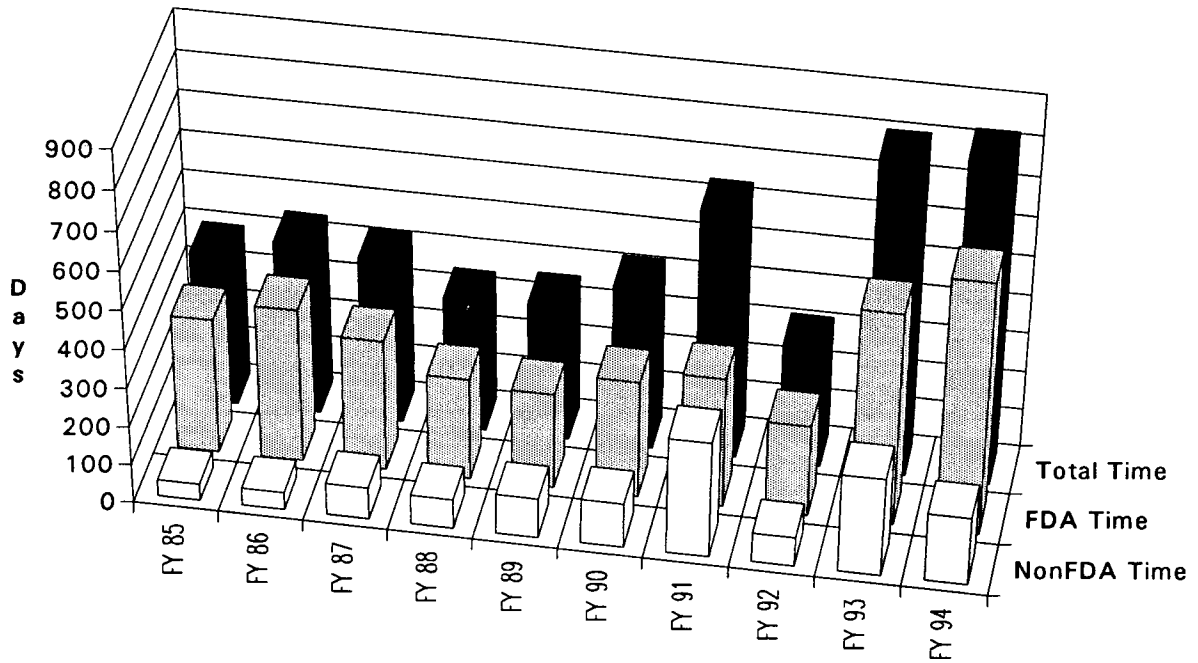


Chart 7. Average Elapsed Time for PMA Approvals



A. Premarket Approval

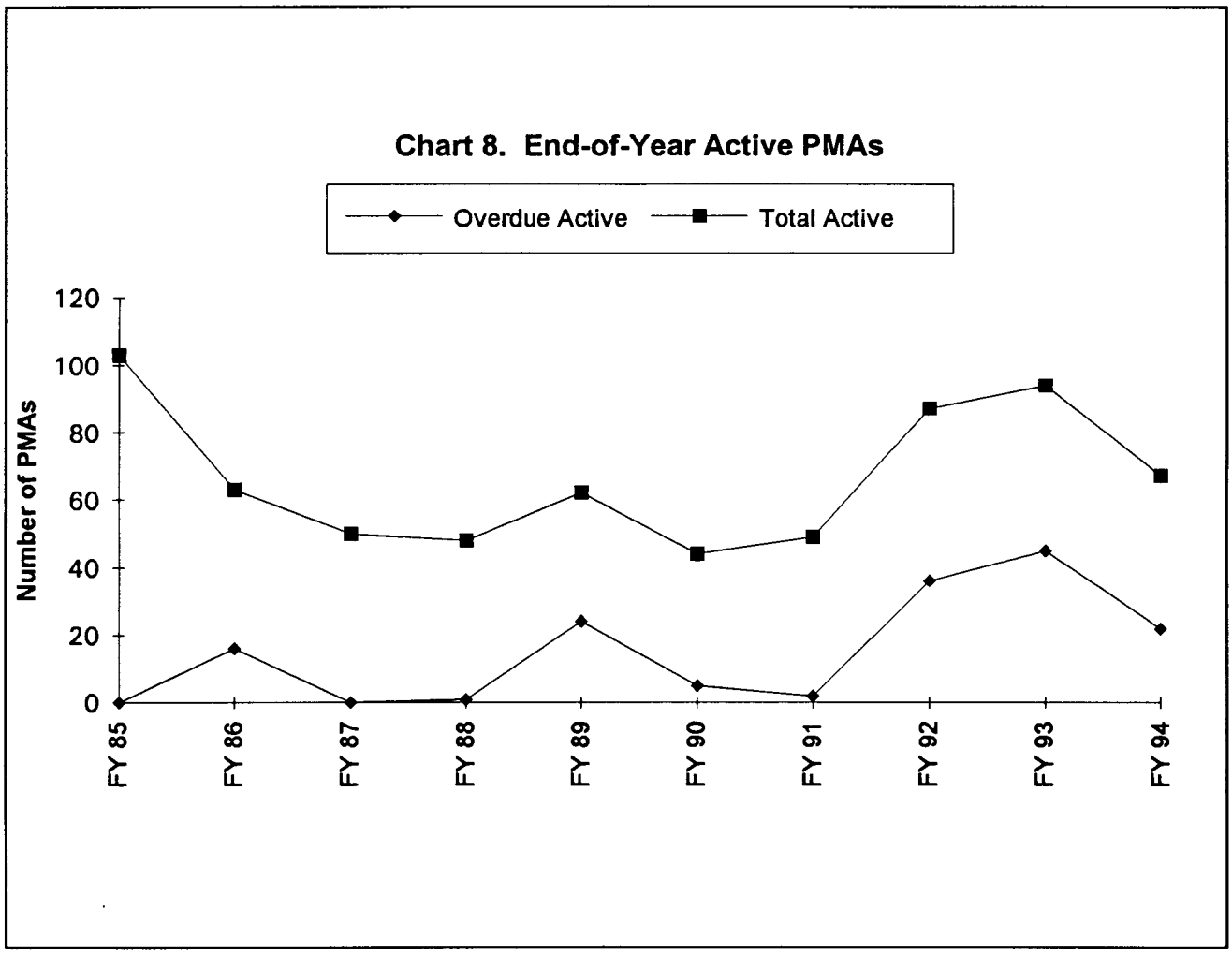
1. Premarket Approval Applications (PMAs)

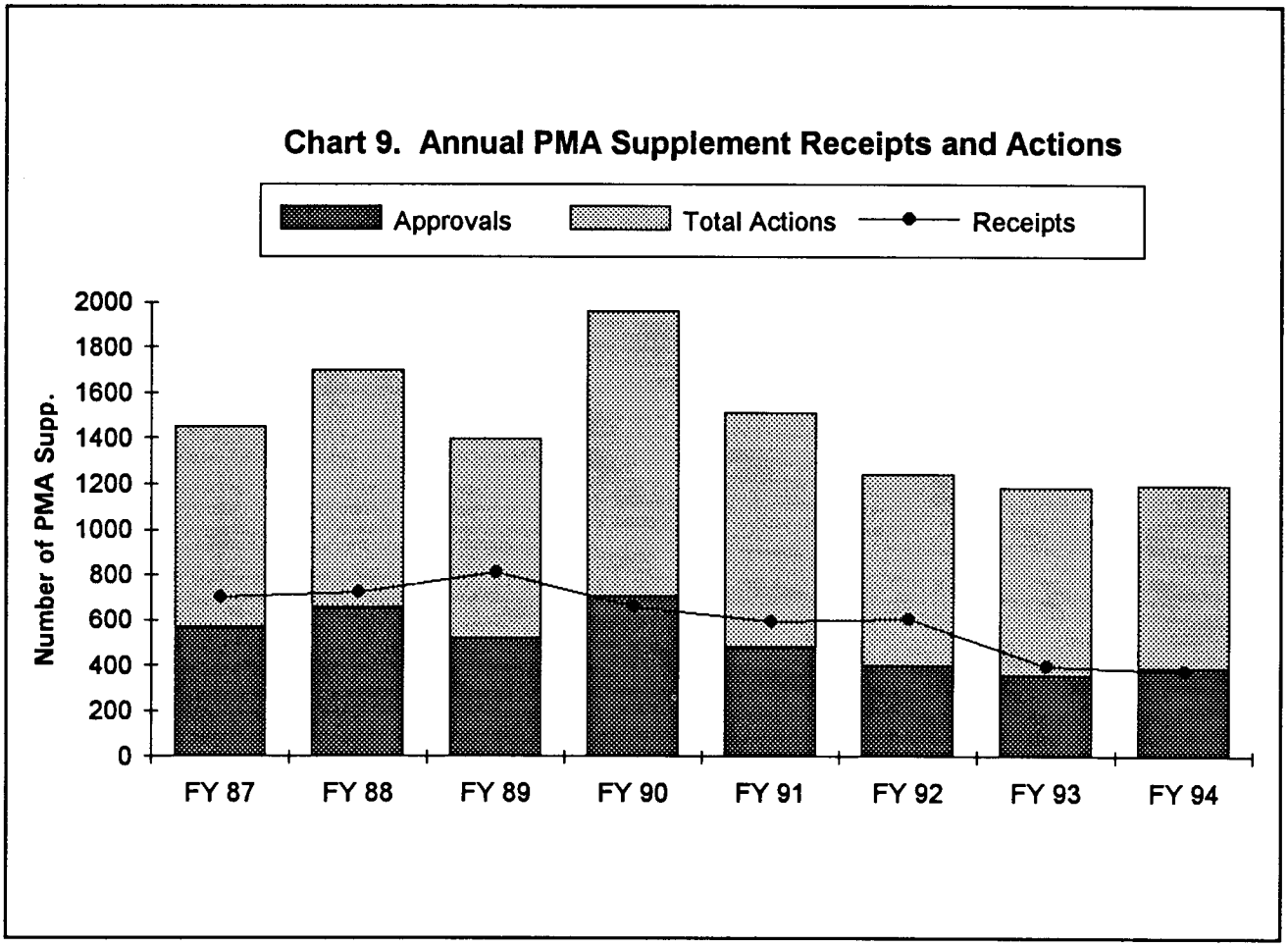
Under the Federal Food, Drug, and Cosmetic Act (the act) and the FDA regulations, *Code of Federal Regulations, Title 21* (the regulations), a manufacturer or others must submit a PMA for FDA review and approval before marketing certain new Class III devices. The PMA must provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufactured 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. 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. This publicly available summary does not include proprietary data or information submitted by the applicant.

During this fiscal year, we received 43 original PMAs, three more than the number received in FY 93. The total number of 354 PMA actions, which includes 63 filing decisions, 225 review activity determinations, and 66 approval decisions, rose 31 from 323 last fiscal year. This rise breaks a two year trend of declining PMA actions.

Twenty six PMAs received final approval, two more than the number of approvals in FY 93. Another 22 original PMAs were found to be approvable. The number of PMAs found to be not approvable dropped from 21 last year to 18 and there were no denials issued during FY 94. In total, the number of PMA decisions remained stable from 68 last year to 66 for this fiscal year.

The increase in these review times is due in large part to the fact that over 45 percent of the PMAs approved during this fiscal year were received during calendar years 1989 - 1991. As older submissions are cleared out, review times necessarily will increase.

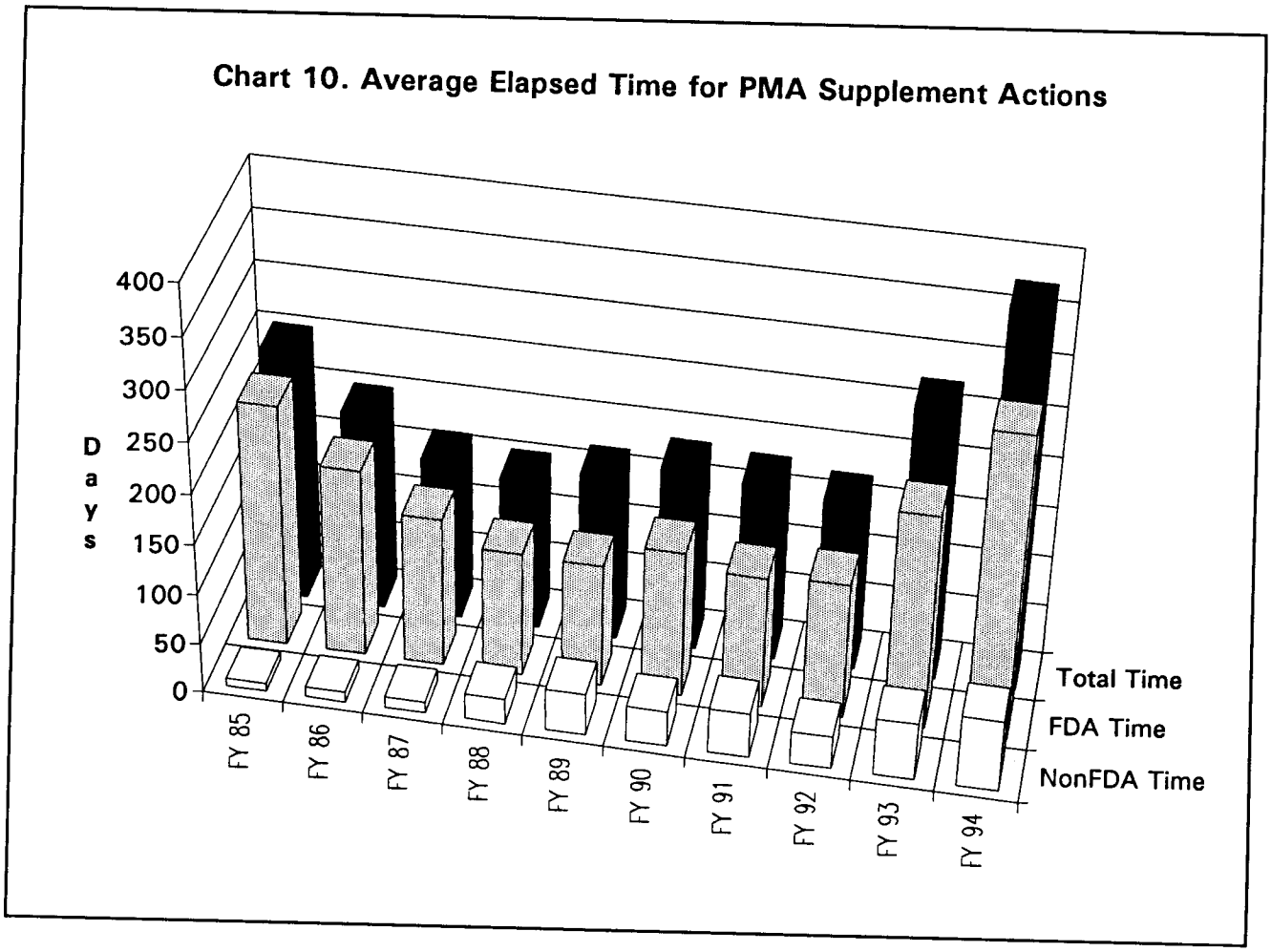




Average FDA review time for original PMAs reaching final action increased from 328 days in FY 93 to 374 days during FY 94. The non-FDA component of review time dropped from 109 days in FY 92 to 78 days this fiscal year. On balance, the combined average review time increased somewhat from 437 days last year to 452 days in FY 94.

Average elapsed time rose from 799 days last year to 823 days in the current reporting period. The FDA component of the elapsed time rose from 547 days in FY 93 to 649 days but the non-FDA component dropped from 252 days in FY 93 to 174 this year.

The total number of PMAs under review at the end of the fiscal year dropped for the second year in a row, from 150 to 139. The active PMAs under review at the end of this fiscal year also went down to 67 from 94 last year, while those on hold increased from last year, from 56 to 72. Fortunately, the number of PMAs that were active and overdue decreased from 45 last year to 22 at the end of FY 94.



2. PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made; for example, actual 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, changes that affect the safety or effectiveness of the device require FDA premarket 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. Many PMA supplements are as complex as the original application.

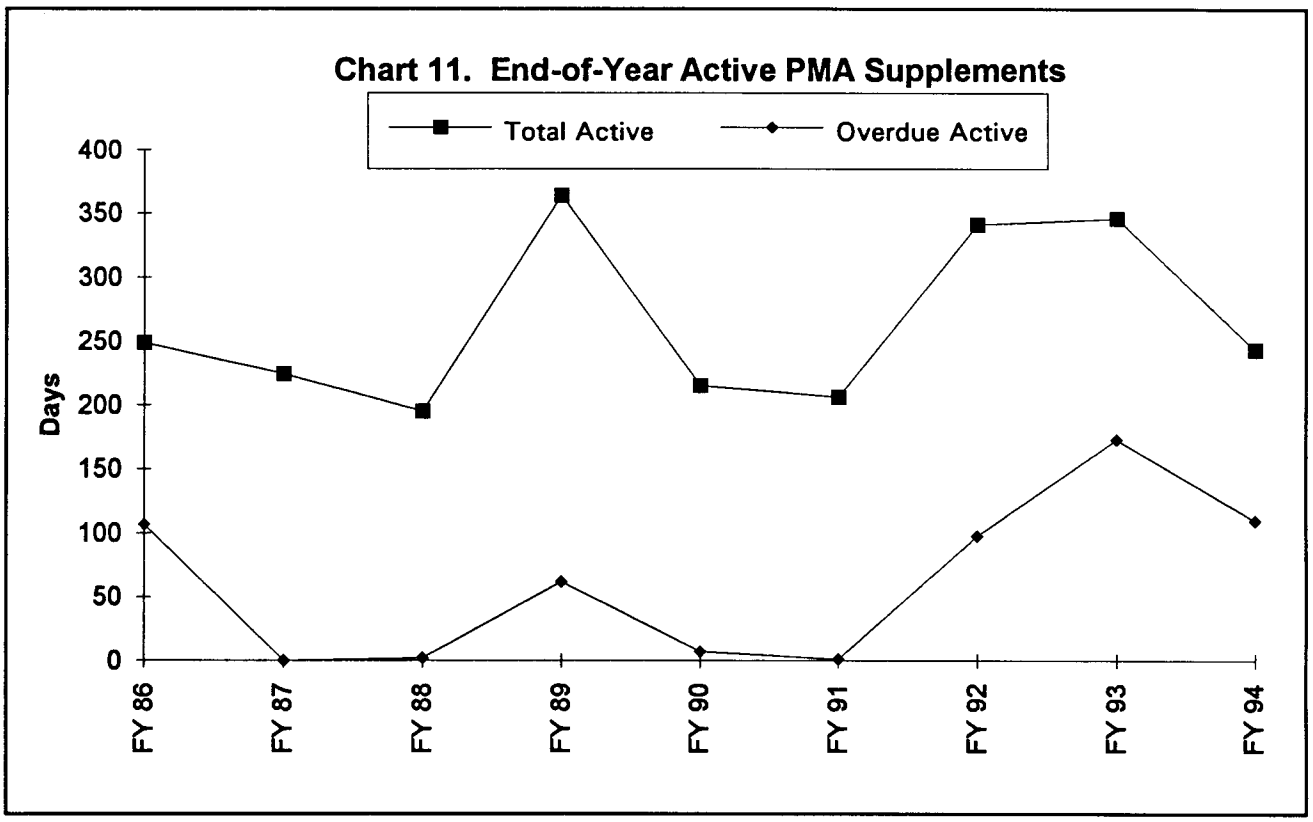
During FY 94, the number of supplements received dropped from last year's 395 to 372, continuing the trend of the last few years of decreasing numbers of PMA supplements. The total number of PMA supplement actions, which includes 5 panel track filing decisions, 220 review activity determinations, and 584 review decisions, also dropped slightly to 809 from last year's 832 total actions.

A total of 385 PMA supplements received final approval. These approvals included three "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 168 days in FY 93 to 253 days this year; combined FDA and non-FDA review time rose from 203 days last fiscal year to 295 days by the end of this year. In addition to the rise in FDA average review time, the non-FDA time increased from 35 days in FY 93 to 42 days in FY 94.

Average elapsed time also jumped from 269 days in FY 93 to 371 days this year, due primarily to the increase in FDA elapsed time from 213 to 301 over the same period of time. Non-FDA elapsed time also rose from 56 to 70 days in FY 94.

The 376 total number of PMA supplements under review at the end of this year represents a significant reduction from last year's 465 and is comparable to the totals in the years before FY 92 and FY 93. The number of PMA supplements that were active and overdue also decreased from 173 at the end of the last fiscal year to 110 at the end of this year. The number of active supplements was further reduced to 243 from 346 last year but the number of supplements on hold rose slightly from 119 to 133 at the end of FY 94.



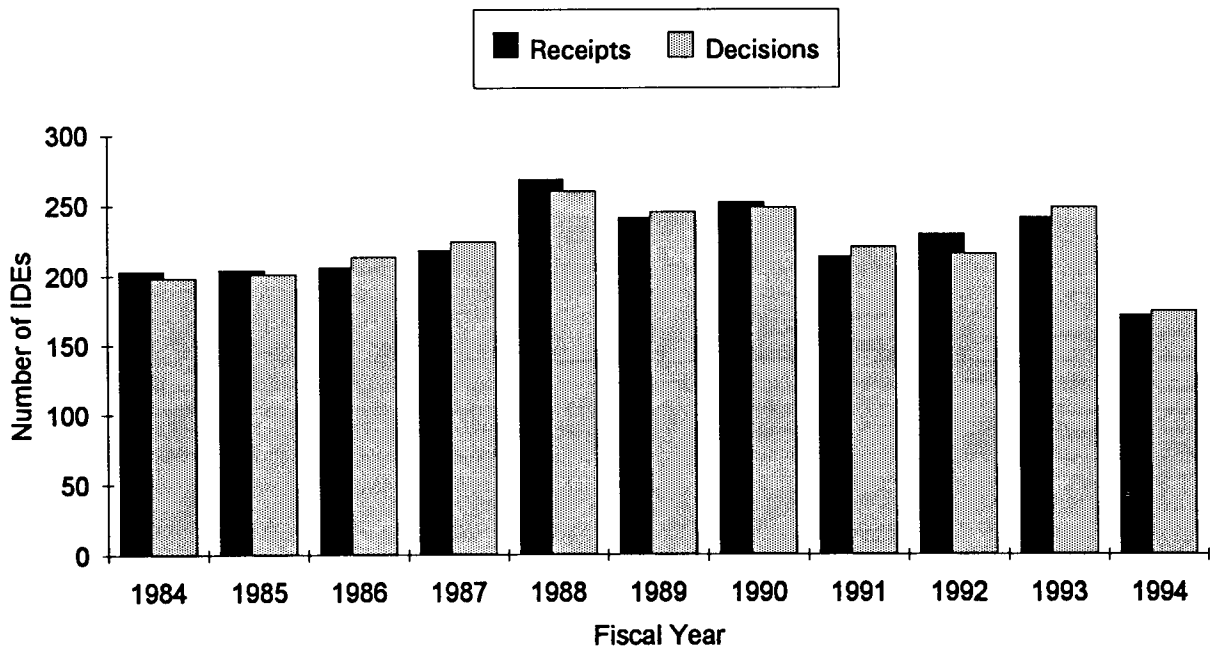
B. Investigational Devices

1. Investigational Device Exemptions (IDEs)

Under the act and regulations, an individual, institution or company 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) as well as informed consent from the study subjects at the time of their enrollment in the study. If the investigational device study presents a significant risk to the subjects, the sponsor also must obtain FDA's approval of the investigational device exemption application (IDE) under 21 CFR 812. The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject informed consent form, device labeling, cost of the device, and other matters related to the study. FDA has 30 calendar days from the date of receipt of the application to approve or disapprove an IDE submission.

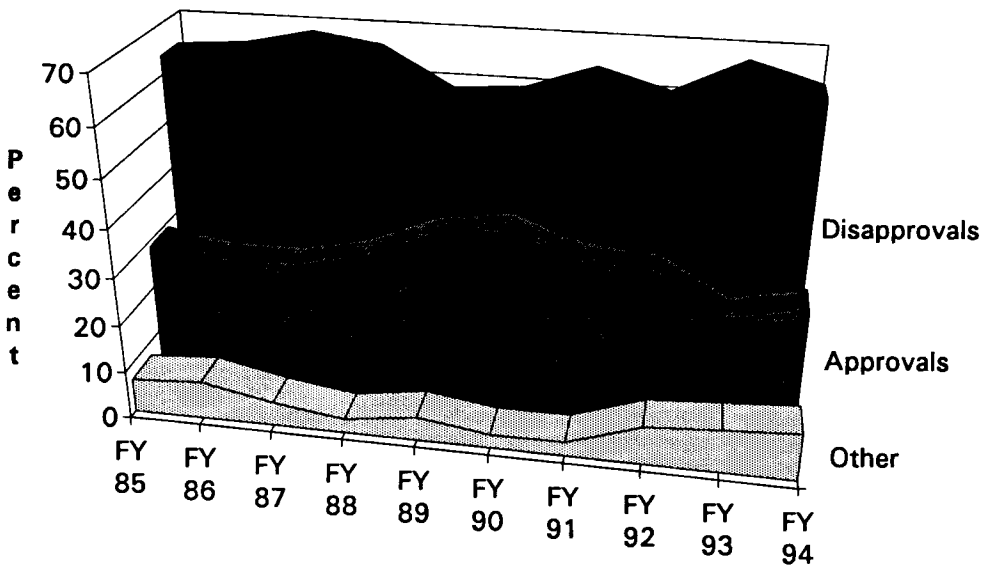
We received 171 original IDEs during FY 94, a significant drop from the 241 received in FY 93. The same holds true for IDE decisions; the 174 decisions made on original IDEs during FY 94 was down from 248 last year. Each fiscal year, the number of decisions made closely parallels the number of documents received, because of the short turnaround time for IDE reviews. The average FDA review time for original IDEs stayed essentially constant at 29 days in FY 94 as compared to 28 days last year. During FY 94, 95 percent of all original IDE decisions were issued within 30 days, down from 97 percent in FY 93.

Chart 12. Annual Original IDE Receipts and Decisions



Of the total decisions made on original IDEs in FY 94, the percentage of decisions that resulted in approval rose for the first time in three years, from 24 percent in FY 93 to 27 percent in FY 94. This is only the second time the percentage of approvals has been below 30 percent since FY 87. It is important that the device industry and ODE do all they can to increase this rate of approval and keep it as high as possible, because of the savings in cost and time for the FDA and industry alike when IDEs are approved on their first submission.

Chart 13. 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". After an IDE is approved, related submissions are are called "supplemental applications" under the regulations. Identification of IDE amendments enables FDA to track each IDE from the time it is originally submitted until the time it is approved.

During this fiscal year we received 254 amendments, down from 320 during the last fiscal year. We made 256 decisions on amendments: 109 approvals (43%); 68 disapprovals (27%); and 77 other administrative actions (30%). Ninety-seven percent of these decisions were made within 30 days.

Each amendment is associated with an original IDE. Thus, approval of an amendment constitutes approval of the IDE, and the proposed investigation may begin. During FY 94, the 109 approved amendments were related to 97 original IDEs, some of which were submitted to FDA prior to FY 94. There were 12 more amendments than original IDEs because some IDEs had more than one amendment.

As stated above, some of the 97 IDEs approved during FY 94 were actually submitted in past years. A total of 220 amendments were submitted in support of these original IDE applications. This averages 2.3 amendments per IDE approved in FY 94.

It took an average total time of 242 days to approve IDEs in FY 94, up from 212 days in FY 93 and only the second time it has exceeded 200 days. This total approval time consisted of 83 days for FDA time, the same as last year, and 159 days for non-FDA time, up from 129 days in FY 93.

Chart 14. Average Approval Time for IDEs with Amendments

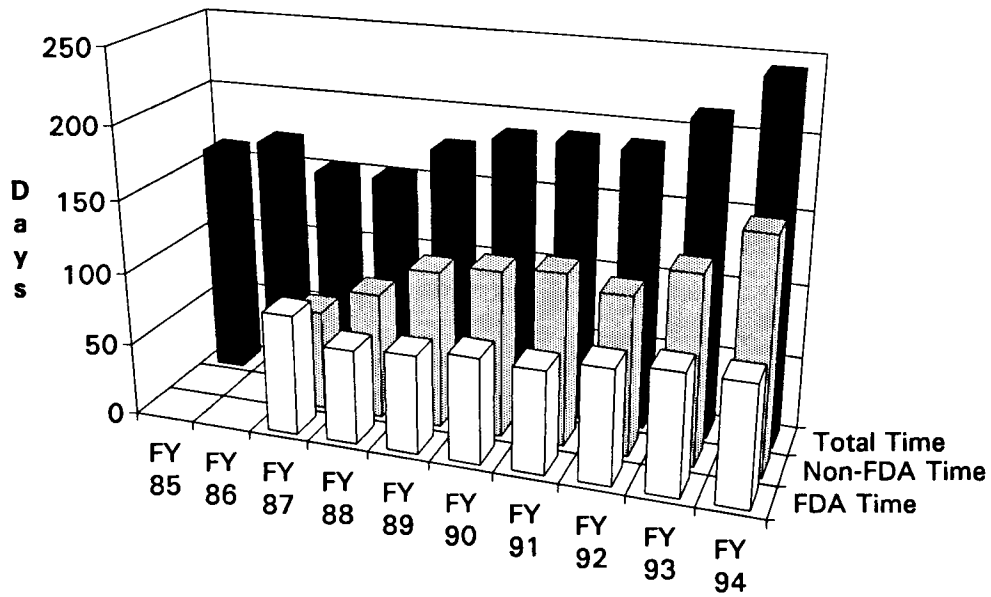
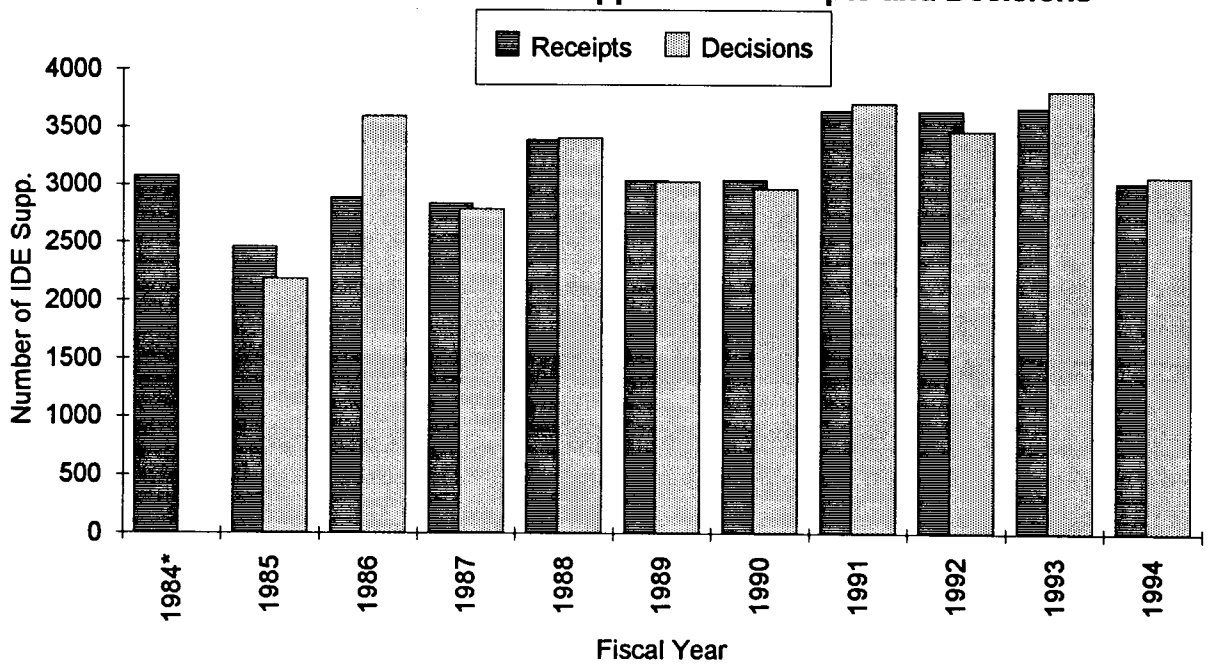


Chart 15. Annual IDE Supplement Receipts and Decisions



* Data on decisions not available.

3. IDE Supplements

The IDE regulation requires the sponsor of an investigation of a significant-risk device to 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. 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 3,020 IDE supplements during FY 94, the lowest since FY 87. There was one overdue supplement at the end of the year, down from eight at the end of FY 93 and the percentage of supplements reviewed within the 30-day statutory time frame increased slightly from 97 percent in FY 93 to 98 percent in FY 94. The average review time for completing the review of IDE supplements dropped to 23 days, reversing a three-year trend of increasing review time.

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 a 510(k) statement, the 510(k) must include data to substantiate the 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 application.

During this reporting period, ODE received 6,434 original 510(k)s and 4,571 510(k) supplements. Original and supplemental 510(k)s totaled 11,005 submissions, an increase of 777 from the 10,228 received in FY 93. The 7,135 decisions rendered on original 510(k)s during FY 94 is an increase of 2,062 (a 41% increase) over FY 93 and represents an all-time record number of 510(k) reviews completed in a single year.

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 time each 510(k) is being reviewed by FDA, plus all the time the 510(k) is on hold while it is under revision by the submitter. The FDA average review time is based only on the total of all of the times each 510(k) is reviewed by

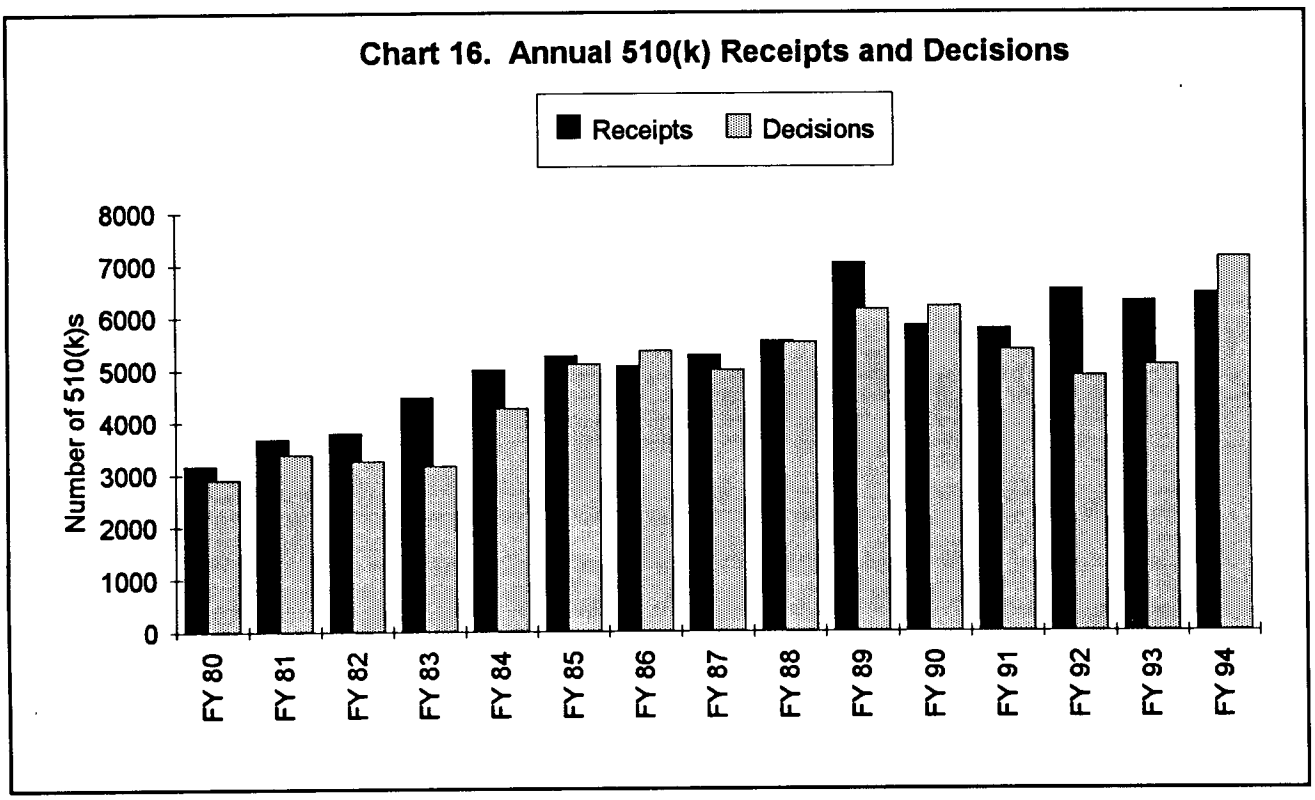


Chart 17. Average 510(k) Review Times

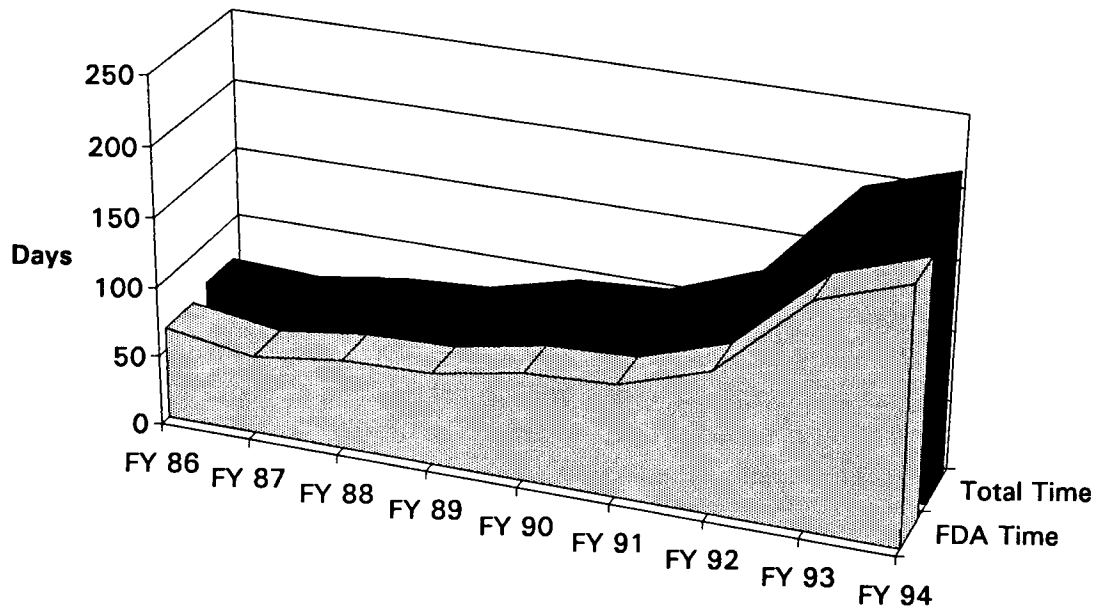
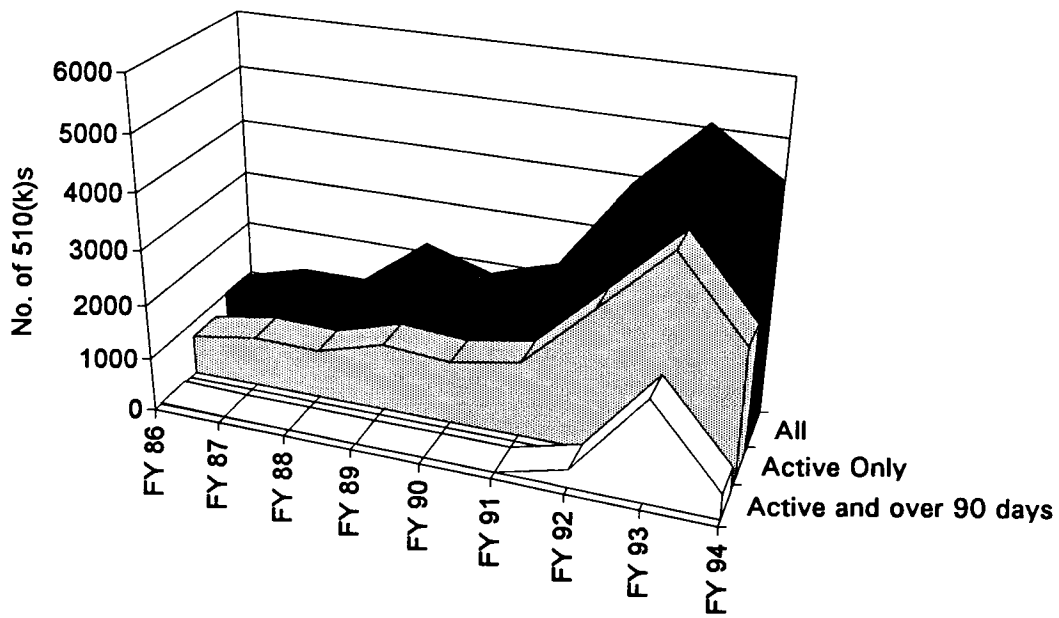


Chart 18. Pending 510(k)s

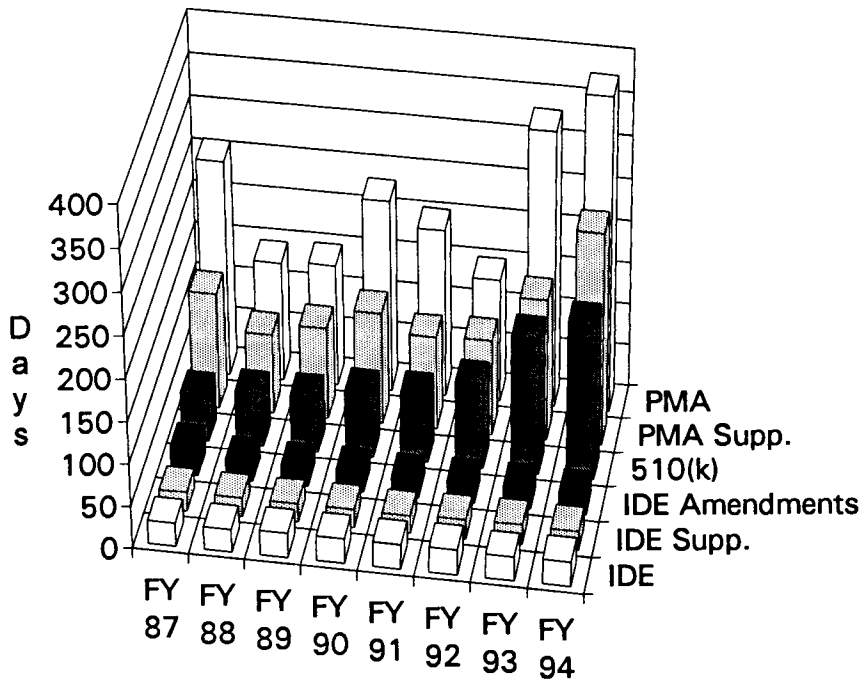


FDA. Both of these average review times rose during FY 94, continuing a four-year trend in increasing 510(k) review times. The total average review time rose from 195 days in FY 93 to 216 days for FY 94 and the FDA review time went up to 184 days from 162 days in FY 93.

The FY 94 Annual Report contains, for the first time, median review times for 510(k)s. These data appear in Table 7, Part VI. Statistical Tables. For FY 94, 50 percent of 510(k)s were completed in 134 FDA review days, compared to 144 days in FY 93. This is the first time the median review time has come down since FY 90. The 510(k)s in the 90th percentile were completed in 396 FDA review days. The median review time based on total time was 155 days and 472 days for the 90th percentile. This modal information based on total review times is a better reflection of what is happening at the present time and should be more useful than average review times 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.

There were 4,374 510(k)s in inventory at the end of this fiscal year, which represents a significant decrease from the 5,157 510(k)s that represented last year's end-of-year inventory. The number on hold, however, rose from 1,335 at the end of FY 93 to 1,960 at the end of this year. Most important, at the end of this reporting period only 460 510(k)s were active and overdue, down from 1,894 in FY 93, a decrease of 76 percent.

Chart 19. Average FDA Review Times



D. Major Program and Policy Initiatives

During FY 94, 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. Addressing Gender-Bias in PMAs.

On June 17, 1994, ODE Divisions were asked to address the possibility of "gender bias" in PMA submissions and Summaries of Safety and Effectiveness Data (SSEDs). The directive provided to ODE review divisions was as follows:

> "Gender bias needs to be addressed in writing in the SSED from two aspects for all pending as well as future PMA submissions.
>
> - Was the selection ratio of men versus women in the study reflective of the underlying distribution of the disease for that given age group, ethnic group, stage of disease, etc.? Was any selection bias on the basis of gender identified during the review?
>
> - Was there any difference in the safety and effectiveness of the device based on gender? For example, was the device more/less effective in women?"

Analyses of these data may be required of the PMA applicant before FDA will approve the application. Because this issue may impact ultimately on approval of the PMA application, the policy recommends that it be addressed as early in the review process as possible for PMAs currently pending. For potential PMAs developed from ongoing studies, applicants are to be informed of this new policy under the IDE or at presubmission meetings.

2. Posting PMA Approval Orders on the CDRH Electronic Docket.

On June 17, 1994, ODE Divisions were asked to make available to the public via the Electronic Docket approval orders for all original PMAs and panel-track supplements. The Electronic Docket is managed by the Division of Small Manufacturers Assistance (DSMA), a part of CDRH's Office of Health and Industry Programs. The electronic version of the letter is to be provided to DSMA after the applicant has been made aware of the approval of its application.

3. PMA Closure.

The PMA Closure Blue Book Memo (#PMA-94-1) is intended to provide guidance on bringing original and panel-track supplement PMAs to closure, i.e., to a final regulatory decision. The Food, Drug, and Cosmetic Act and the PMA procedural regulations establish that PMAs are to be reviewed in 180 days after FDA receipt of a PMA that meets the established content requirements. This Blue Book Memo describes the careful planning by ODE management and reviewers

throughout the "lifecycle" of the application that must be employed to ensure that critical milestones are reached and that final regulatory action is taken in a timely and efficient manner. Under this policy, if the panel recommends "approval" or "approval with conditions" and FDA agrees with the recommendation, ODE division directors should be committed to finalizing the approval package, and then issuing the approvable letter, within 30 days post-panel. The approval order should be issued soon after receipt of the final response from the applicant assuming that the response does not constitute a major amendment.

4. Preamendments Class III Strategy document.

On May 6, 1994, FDA made available a document that sets forth the agency's strategy for implementing the provisions of Section 515(i) of the Safe Medical Devices Act of 1990 (SMDA) which require FDA to review the classification of preamendments class III (premarket approval) devices, and either reclassify the devices into class I (general controls) or class II (special controls) or retain them in class III. The Preamendments Class III Devices Strategy Document schedules the review of 117 preamendments class III devices on which FDA has not initiated any 515(b) rulemaking procedures. The 117 devices have been divided into three groups, using the potential for reclassification as the criterion. High priority Group 3 devices are those determined currently to present an unreasonably high risk to public health because significant issues of safety and/or effectiveness are not being resolved or, to the best of FDA's knowledge, have little probability of being resolved. CDRH will initiate 515(b) rulemaking for fifteen high priority Group 3 devices according to a schedule presented in the strategy document.

CDRH will issue an order for the remaining Group 3 devices that are not considered good candidates for reclassification, requiring manufacturers to submit all safety and effectiveness information available or known to them including adverse information. CDRH will review and evaluate the safety and effectiveness information and proceed with rulemaking to reclassify the devices or retain them in class III and schedule section 515(b) rulemaking for those devices retained in class III.

CDRH will also issue an order for Group 2 devices, devices deemed likely candidates for reclassification. The information will be evaluated as described above; the Group 2 devices will be reclassified and the schedule for 515(b) rulemaking included in the strategy document will be revised for those devices retained in class III.

CDRH will propose 515(b) rulemaking for a group of devices that have fallen into disuse or are rarely in current use, designated as Group 1.

5. Exemption of Tier 1, Class I Devices.

In the July 21, 1994, issue of the *FEDERAL REGISTER*, FDA proposed to exempt 164 generic types of class I devices from the premarket notification requirement, subject to certain limitations.

For the devices proposed for exemption, FDA has determined that premarket notification is not necessary for protection of the public health. Further, the agency will be able to more efficiently allocate the resources available for its public health mission. The devices proposed for exemption had all been determined to be Tier 1 devices by ODE review divisions during a triage effort early in 1994 that resulted in grouping devices into Tiers depending upon risk assessment and the depth of review necessary to provide a reasonable assurance of safety and effectiveness. Tier I devices present a low risk to public health and require only a labeling review. A final rule will be prepared and published after the comment period which will address all comments submitted.

6. Office Move.

In late FY 94 ODE began its move into new offices. During the weekend of June 10-12, 1994, the Division of Clinical Laboratory Devices moved from 1390 Piccard Drive to 2098 Gaither Road, Rockville, Maryland 20850. Immediately after the close of the fiscal year, the remainder of ODE moved from the same location to 9200 Corporate Boulevard, Rockville, Maryland 20850.

7. Contracting Out Document Mail Center.

On september 1, 1994, KRA Corporation, a private corporation, was engaged to operate the Office of Device Evaluation Document Mail Center (DMC) and the CDRH mail center. The ODE staff members who previously operated the DMC have been reassigned to ODE review divisions to assist in reviewing and processing marketing applications.

E. Significant Medical Device Breakthroughs

- On January 10, 1994, CIBA Vision Corporation's P900029 was approved for the NDS System (consisting of the NDS starting solution and NDS finishing solution). A unique feature of this two-step disinfection system is that it requires a total time of only five minutes to complete the disinfection process.

- On March 1, 1994, Polymer Technology Corporation's P860022/S40 was approved for the Boston Scleral Lens, which incorporated a vaulted design made from a rigid, highly gas-permeable material. This lens protects the cornea from trauma in patients with severely scarred, irregular and sensitive corneas caused by severe keratoconus or dry eyes who cannot use spectacles or conventional contact lenses.

- On March 29,1994, the Cidex product line of general-purpose liquid sterilants by Johnson and Johnson Medical, Inc. was cleared. These products represent the first devices cleared under the conditions of the Memorandum of Understanding between EPA and FDA concerning sterilants.

- On April 20, 1994, the Parastep-I System by Sigmedics, Inc., P900038, was approved. The Parastep-I System is a functional neuromuscular stimulator with surface electrodes for the lower extremities and with controls incorporated into a mechanical walker. This

device offers significant quality-of-life improvement and functional improvement to spinal-cord-injured patients in that it allows them to stand or to stand and take steps without having to wear cumbersome and visibly obvious long leg braces. It allows patients to stand up and reach high objects for functional purposes and to walk into places that might not be accessible to a wheelchair, e.g., a bathroom that does not accommodate a wheelchair.

- On April 26, 1994, CARDIAC T™ ELISA Troponin-T was cleared for marketing. Troponin-T is a marker used to aid in the diagnosis of acute myocardial infarction in serum with better cardio-specificity than creatine kinase MB. In this in-vitro diagnostic assay, the TN-T marker is detectable as long as 14 days post-infarct.

- On May 26, 1994, Allergan Medical Optics' P890056 was approved for the Model PC-28LB Posterior Chamber Intraocular Lens. This is a "first-of-a-kind" technology - a hard IOL that includes wings on the side that bend in on themselves to allow insertion through a smaller incision than other lenses. Although this PMA was recommended for approval by the Ophthalmic Devices Panel on April 19, 1990, the company incurred GMP delays that delayed final approval.

- On June 28, 1994, Toray's Inoue Balloon Catheter, P910054, was approved. It is the first device approved for percutaneous transvenous mitral commissurotomy in patients with hemodynamically significant mitral valvular stenosis resulting primarily from commissural fusion of the mitral valve cusps.

- On July 11, 1994, Allergan Optical's P850088/S30 was approved for a revised formulation for the Oxysept Neutralizer Tablet that includs cyanocobalamine (vitamin B12) as a color-indicator safety feature for use in the Oxysept Disinfection System. The color-indicator neutralizer tablet turns the hydrogen peroxide disinfecting solution pink to indicate that the neutralizer tablet has been added, thereby minimizing the possibility of placing an un-neutralized contact lens on the eye.

- On August 2, 1994, Johnson & Johnson Interventional System's Palmaz-Schatz Balloon-Expandable Stent, P900043, was approved. It is the first stent to be indicated for use following percutaneous transluminal coronary angioplasty procedure for the de novo treatment of a coronary artery lesion when residual stenosis is greater than or equal to fifty per cent.

- On August 5, 1994, FDA approved P900059 by Molecular Biosystems, Inc., for Albunex Ultrasound Microspheres. Albunex is intended as an aid for ultrasound contrast enhancement of ventricular chambers and improvement of endocardial border definition in patients with suboptimal echoes undergoing ventricular-function and regional-wall motion studies. This is the first device of its kind to receive marketing approval from FDA.

- On August 23, 1994, the Endopath Optical Obturator was cleared for marketing. This obturator incorporates an optical element at the distal end of the device and provides a capability for direct viewing of the placement of the trocar in laparoscopic procedures. This design represents a first-of-a-kind for this type of device.

- On August 25, 1994, the Hybritech Tandem®-R.E. and ERA PSA Assay, P850048/S9, was approved for a modification to the original intended use. This device is indicated for the measurement of serum PSA in conjunction with digital rectal examination as an aid in the detection of prostate cancer in men aged 50 years or older. Prostate biopsy is required for the diagnosis of cancer. The device was originally approved for use as an aid in the prognosis and management of patients with prostate cancer.

- On September 30, 1994, Endosonics' Oracle™ Micro PTCA Catheter, P910031, was approved. It is indicated in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery, and who meet certain selection criteria and is an adjunct to conventional angiographic procedures. This is the first device that combines an ultrasound detector as part of the balloon angiography system.

- On September 30, 1994, the Thermocardio Systems, Inc. Heartmate® IP Left Ventricular Assist System, P920014, was approved. This device is used to provide temporary mechanical circulatory support for approved cardiac transplant candidates who have nonreversible left ventricular failure and is the first device to serve as a bridge to cardiac transplantation.

- On October 20, 1994, the FDA cleared AVL Scientific Corporation's BGK1 pH/Blood Gas Analyzer, the first in-vitro diagnostic use of fluorescent optic electrode (optode) technology in blood gas determinations. This technology is currently used in extracorporeal blood gas monitoring of arterial and venous blood.

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. The 58 such documents produced in FY 94 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 these guidance documents are made available by the Division of Small Manufacturers Assistance (HFZ-220) on the Center's Electronic Docket, a computer-based bulletin board system, via telefax and in hard copy at: ELECTRONIC DOCKET (BBS): (800) 252-1366 or (301) 594-2741; FACTS-ON-DEMAND (telefax): (800) 899-0381 or (301) 827-0111; MAIL: 1350 Piccard Drive, Rockville, Maryland 20850-4307; or, VOICE: (800) 638-2041 or (301) 443-6597.

Guidance Documents Issued During Fiscal Year 1994

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

  Documentation and Resolution of Differences of Opinions on Product Evaluations. This guidance, issued on December 23, 1993, describes the respective roles of Center staff members who review, consult on, or otherwise provide input on a review document; other FDA employees; and, special government employees, supervisors and management in the document review processes for 510(k)s, IDEs, and PMAs -- and states how institutional positions are reached on review decisions. The guide also indicates how each person in the review chain is to document his views and the procedure for resolution of differences of opinion when these arise.

  PMA Refuse to File Procedure. The purpose of this policy, issued on May 20, 1994, is to clarify existing procedures under which a PMA that does not meet a minimum threshold of acceptability will not be accepted for substantive review.

  510(k) Refuse to Accept Procedure. The purpose of this May 20, 1994, 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.

  IDE Refuse to Accept Procedure. The purpose of this policy, issued on May 20, 1994, is to establish procedures under which an IDE that does not meet a minimum threshold of acceptability will not be accepted for substantive review.

510(k) Sign-Off Procedures. This June 3, 1994, memo establishes new ODE sign-off procedures for 510(k) final decision letters and requests for additional information. These procedures delegate sign-off authority to Division Directors for all final decision letters, including NSE letters and special SE letters, which had previously been reserved to the Deputy Director of ODE. It rescinds and replaces Blue Book Memorandum K86-2, 510(k) Sign-Off Procedures.

PMA/510(k) Triage Review Procedures. The purpose of this "triage" proposal, which was issued on May 20, 1994, is to establish a three tier-system using risk assessment to more-effectively manage the review workload and allocate review resources.

PMA/510(k) Expedited Review. The purpose of this May 20, 1994, proposal is to establish criteria and procedures under which expedited review would apply to PMAs and 510(k)s based upon a device's potential for clinically meaningful benefit as compared to existing modalities or a new medical device that promises to provide a revolutionary advance over currently available alternatives.

Premarket Approval Application (PMA) Closure. This memo, issued on July 8, 1994, provides guidance on reaching a final decision on PMAs and PMA Supplements in an efficient manner.

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

Nebulizers, Metered Dose Inhalers, Spacers, and Actuators. In October 1993, DCRND revised the Draft Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers, and Actuators. This revision incorporated more-specific bench testing for each device.

Premarket Notification Submissions. During November 1993, DCRND issued a revision of the Draft Reviewer Guidance for Premarket Notification Submissions. This document was updated to reflect current procedures and alterations to test methods.

Intra-Aortic Balloon Catheters. In December 1993, the Draft Guidance for Determining Equivalence of Intra-Aortic Balloon Catheters under the 510(k) Regulations was revised. The purpose of the revision is to produce one document that applies to both intra-aortic balloon catheters and the consoles used to drive the catheters, to provide guidance for the mock loop used for evaluating the catheters and the console, and to provide guidance for conducting abrasion testing of the catheter balloon material.

Replacement Heart Valves. December 1993, a major revision of the Guidance for Replacement Heart Valves was issued. This revision outlines preclinical and clinical study recommendations for tissue and mechanical heart valves.

Peak Flow Meters. In January 1994, DCRND issued the Draft Guidance on 510(k) Content for Peak Flow Meters. This document is to be used in conjunction with the Draft Reviewer Guidance for Premarket Notification Submissions and contains specific recommendations for 510(k) submissions for peak flow meters.

Rechargeable Battery. During January 1994, DCRND issued a draft Rechargeable Battery Preliminary Guidance for Data to be Submitted to the Food and Drug Administration in Support of Premarket Notification Applications. This document was developed to provide a description of the information that FDA recommends to support a 510(k) application.

Coronary and Cerebrovascular Guidewire. In March 1994, DCRND issued a Coronary and Cerebrovascular Guidewire Guidance. This document is intended to outline the types of scientific data considered necessary for submission in an investigational device exemption (IDE) application, when applicable, and in a 510(k) application.

Face Masks and Shields for CPR. During March 1994, DCRND issued the Draft Reviewer Guidance on Face Masks and Shields for CPR. This document is to give guidance on the information to be included in 510(k) submissions and will be used by FDA to review them.

Interventional Cardiology Devices. On May 1994, DCRND issued a revision of the Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, and Intravascular Stents. Earlier guidance was submitted to industry for comments, then revised to incorporate changes in animal studies and clinical sections.

Neural Endoscope. In July 1994, DCRND issued Draft Neural Endoscope Guidance. This is to be used in conjunction with the Division Draft Reviewer Guidance for Premarket Notification Submissions. This document outlines specific information to be submitted for premarket notification submissions for neurological endoscopes.

Cranial Perforator. During July 1994, DCRND issued a Draft for Cranial Perforator Guidance. This document is to be used in conjunction with the general information outlined in the Division Draft Reviewer Guidance for Premarket Notification Submissions. This document outlines specific information to be submitted for cranial perforators, craniotomies and motor drives.

Cranial Electrotherapy Stimulators. On August 1994, DCRND issued the Guidance for Clinical Data to be Submitted for Premarket Approval Applications for Cranial Electrotherapy Stimulators. The purpose is to give guidance on the type of data required in premarket approval applications.

Cortical Electrode. In August 1994, DCRND issued a Guide for Cortical Electrode 510(k)s. The purpose of this guideline is to recommend the type of information to be included in 510(k) applications for cortical electrodes.

Biofeedback. In August 1994, DCRND issued Biofeedback Devices - Draft Guidance for 510(k) Content. This document is to be used in conjunction with the Division Draft Reviewer Guidance for Premarket Notification Submissions. It also provides more specific guidance for 510(k)s that claim equivalence to biofeedback devices.

TENS 510(k)s. During August 1994, DCRND revised the Draft Guide for TENS 510(k) Content. The purpose of the revision was to incorporate new material related to safe patient leads and electromagnetic interference.

Galvanic Skin Response Measurement Devices. In September 1994, DCRND issued the Draft Guidance for Galvanic Skin Response Measurement Devices. This document provides guidance for the content of premarket notification submissions.

Biocompatibility Requirements for Long-term Neurological Implants. On September 1994, DCRND issued the Draft Guidance on Biocompatibility Requirements for Long-term Neurological Implants. The purpose is to give general guidance to industry on the specialized biocompatibility testing requirements for implanted neurological devices. These requirements are in addition to the applicable tests listed in the tripartite biocompatibility guidance.

Autotransfusion Components/Systems. In September 1994, DCRND developed a Draft Guidance for the Preparation and Content of Premarket Notification Applications to FDA for Autotransfusion Components/Systems. The purpose is to give guidance to industry on the type of information required for a complete premarket notification submission.

Ambulatory Electrocardiograph. During September 1994, DCRND issued a Draft of Ambulatory Electrocardiograph Preliminary Guidance for Data to be Submitted to the Food and Drug Administration in Support of Premarket Notification Applications. This document was developed to provide a description of the information that FDA recommends to support a 510(k) application.

External Cardioverters and Defibrillators. On September 1994, DCRND revised the draft Preliminary Guidance for Data to be Submitted to the Food and Drug Administration in Support of Premarket Notification Applications for External Cardioverters and Defibrillators. This document was revised to incorporate additional testing requirements.

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

Thyroid Autoantibodies. In February 1994, DCLD issued the Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination (IHA), Radioimmunoassay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA). This document provides guidance about the information needed by FDA to clear in-vitro diagnostic devices to detect, quantitate and/or semi-quantitate thyroid autoantibodies in clinical specimens by IFA, IHA, RIA, or ELISA.

Mycobacterium tuberculosis (Addendum). In February, 1994, DCLD issued an addendum to the Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. FDA includes the following additional information to assist sponsors in the collection of data and clinical information to assess the safety and effectiveness of a new device for the detection of Mycobacterium tuberculosis.

Nucleic Acid Amplification/Infectious Microorganisms. In June 1994, DCLD issued the Review Criteria for Nucleic Acid Amplification-Based In Vitro Diagnostic Devices for Direct Detection of Infectious microorganisms. This document provides guidance about the information needed by FDA to approve or clear in-vitro diagnostic devices for direct detection of microbial nucleic acids in clinical specimens. These qualitative assays are intended as an adjunct to culture (or other "gold standard" as appropriate).

Alpha-fetoprotein. In July 1994, DCLD issued the Review Criteria for Assessment of Alpha-fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies. This document provides guidance about information needed before FDA can issue an approval order for marketing such a device.

Cervical Cytology. In July 1994, DCLD issued Points to Consider for Cervical Cytology Devices. This document provides guidance about information needed before the FDA can issue an approval order for marketing in-vitro diagnostic cytology devices for gynecological specimens.

Immunohistochemistry Products. In July 1994, DCLD issued Points to Consider for the Submission of Immunohistochemistry Applications to the FDA. This guidance assists manufacturers in preparing in-vitro diagnostic device submissions for immunohistochemical products. The emphasis is on products using monoclonal antibody reagents.

510(k) Data. In September 1994, DCLD issued Points to Consider for Collection of Data in Support of In Vitro Diagnostic Device Submissions for 510(k)s. This guidance is intended to supplement, but not replace, existing FDA guidance for 510(k)s.

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

Electrosurgical Devices. In October 1993, DGRD issued 510(k) Guidance for General Surgical Electrosurgical Devices, outlining the information that must be addressed in 510(k) applications for such devices.

Saline-Filled Silicone Breast Implants. On December 10, 1993, DGRD issued Guidance Document for Preparation of Premarket Approval (PMA) Applications for Silicone Inflatable (Saline) Breast Prostheses, which contains a description of the preclinical and clinical requirements for consideration of a submission.

Orthopedic Device 510(k)s. On January 21, 1994, DGRD revised the draft guidance document for the preparation of 510(k) applications for orthopedic devices. The guidance contains a description of the administrative, scientific, and regulatory content needed for a complete 510(k) application and was revised to include an updated list of guidance documents available for orthopedic devices.

Sharps Injury Prevention Feature Guidance. In February 1994, DGRD Pilot issued supplementary guidance on the content of Premarket Notification Submissions for Medical Devices with Sharps Injury Prevention Features. This supplemental guidance is intended to assist in assembling and organizing premarket notifications for devices incorporating a sharps injury prevention feature and specifies the types of data to be included in such submissions.

Orthopedic Implant Test Data. On April 28, 1994, DGRD revised the "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement" to reduce the amount of data required in 510(k) applications for some of the more common types of porous coatings.

Arthroscope 510(k)s. In May 1994, DGRD drafted a guidance document for the preparation of 510(k) applications for arthroscopes and arthroscope accessories. The administrative, scientific, and regulatory contents required for a complete 510(k) application are described in this document

Temporomandibular Joint Implants. On June 1, 1994, DGRD Pilot issued guidance for the preparation of premarket notifications for temporomandibular joint implants. This draft guidance specifies the types of data to be included in 510(k) submissions. In the Federal Register, on December 20, 1994, temporomandibular joint implants were classified into class III.

Labeling Wheelchairs/Scooters for EMI. On May 26, 1994, DGRD issued Electromagnetic Compatibility of Powered Wheelchairs and Motorized Scooters Labeling Guidance, which discusses concerns the agency has regarding this issue, and describes information manufacturers must include in their labelling of these devices.

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

510(k) Guidance for Class II Contact Lenses. Issued Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lens and a revised edition in May 1994, containing the special controls determined to be necessary for providing reasonable assurance of safety and effectiveness of Class II Contact Lenses.

Labeling for Class III Contact Lenses. On March 8, 1994, DOD issued procedures for adding the monovision fitting technique to the labeling of Class III single-vision contact lenses for the management of presbyopia by submission of a 30-day PMA supplement.

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

Picture Archiving and Communications Systems (PACS). In August 1993, DRAERD issued the updated Guidance for the Content and Review of 510(k) Notification for Picture Archiving and Communications Systems (PACS) and Related Devices. PACS are systems intended to provide transmission, storage and viewing facilities for medical diagnostic images at distributed locations. This guidance is applicable to picture archiving and communications systems (PACS) and to related devices that perform one or more of the functions (i.e., image transmission, storage or viewing) that may be provided in a PACS. The guidance does not apply to general-purpose devices if they are not specifically indicated or promoted for use in conjunction with medical images. (Though this guidance was released in FY93, it was not included in the FY93 Annual Report. It is an update from February 1991 guidance.)

Vasovasotomy. 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 the use of a device for vasovasotomy.

Latex Condoms. On March 24, 1994, DRAERD issued the Draft Information for a Latex Condom 510(k) Submission For Obstetrics-Gynecology Devices Branch. This information is a compilation of previous information required of manufacturers who submit premarket notification 510(k)s for latex condoms. The compilation consists of: requirements for Device Description and Material Safety, Quality Assurance, Labeling, Shelf Life, and Safe Medical Device Act Requirements. Included in the requirements are the following documents: FDA's Tripartite Biocompatability for Medical Devices Guidance [for selection of the appropriate type of tests]; FDA's Medical Alert, "Allergic Reactions to Latex-Containing Medical Devices"; International Organization for Standardization (ISO 4074-1:1990(E) Rubber Condoms - Part 6: Determination of Bursting Volume and Pressure (ISO 4074-6:1984; American Society for Testing Materials, Standard Specification for Rubber Contraceptives (Condoms) (ASTM D 3492-89); FDA's letters to manufacturers dated April 7, 1987, July 31, 1987, February 13, 1989 and April 8, 1993; Information for Condoms with a Spermicidal Lubricant 510(k) Submission for Obstetrics-Gynecology Devices Branch; FDA's October 16, 1989 letter regarding Expiration Date of Condoms; and October 1989 General Guidance for Modifying Condom Labeling to Include Shelf Life.

Hemodialyzer Reuse Labeling. On March 27, 1994, DRAERD issued the Fifth Draft of the Guidance for Hemodialyzer Testing, With Special Instructions for Reuse Labeling. FDA has determined that the actual intended clinical use practice for hemodialyzers in the United States of America has changed from single use to one of reuse on the same patient. Manufacturers of hemodialyzers who currently distribute to facilities that reuse dialyzers, or have knowledge the their dialyzers are being clinically reused, must provide, in accordance with

21 CFR 801.4, adequate labeling to the health care provider to allow for the safe and effective reuse of the device. Hemodialyzers will no longer be generally allowed, as a group of devices, to be labeled "For Single Use Only". Therefore, all hemodialyzer labeling, both for new hemodialyzers and approved hemodialyzers, must provide scientifically obtained and validated guidance information to the health care provider as to the limitations of reuse, and, when appropriate, the methods of performing safe and effective dialyzer reprocessing for use of the device on a single patient. The purpose of this guidance is to provide guidance to manufacturers for reuse labeling of hemodialyzers.

Hysteroscopes, Laparascopes, Hysteroscopic Insufflators, Laparoscopic Insufflators and Other Related Instrumentation. On March 30, 1994, DRAERD issued the Draft Guidance for Submission Requirements for 510(k)s to Manufacturers of Hysteroscopes, Laparascopes, Hysteroscopic Insufflators, Laparoscopic Insufflators, and Other Related Instrumentation. The guidance is intended to provide current reviewer expectations for information to be included in a 510(k) for such devices.

Simplified Radiology Devices. On December 21, 1993, January 31, 1994, and March 31, 1994, DRAERD issued guidance letters for Simplified 510(k) Submissions for certain radiology devices (x-ray and CT devices). These three letters, sent to the National Electrical Manufacturers Association (NEMA), outline information that manufacturers must supply in order to comply with the requirements.

Revision of Diagnostic Ultrasound (4/14/94). On April 14, 1994, DRAERD issued a revision of its 1993 Guidance on Diagnostic Ultrasound 510(k) Submissions. This revision allows the use of the mechanical index (MI) in place of the derated spatial peak, pulse average intensity (ISPPA). CDRH has determined that the preamendment values of MI are 1.9 for general ultrasound devices and 0.23 for opthalmic ultrasound devices.

Revision of Diagnostic Ultrasound (4/15/94). On April 15, 1994, DRAERD issued a revision of Section 4.4 of the 1993 Guidance on Diagnostic Ultrasound 510(k) Submissions. This revision addresses the labeling required for transducers that are reusable and supplied nonsterile. The manufacturer is required to provide instructions on recommended methods for cleaning and, where appropriate, either disinfection or sterilizing that transducer between uses. These recommended procedures should be validated and summary information supplied in the submission.

Urine Drainage Bags. On June 2, 1994, DRAERD issued the Guidance for the Content of Premarket Notifications for Urine Drainage Bags. This guidance document describes examples of devices within this generic type. Its purpose is to provide manufacturers with information needed in order to document substantial equivalence to a device in commercial distribution. Substantial equivalence is to be established with respect to, but not limited to, intended use, design, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

Testing Guidance for Non-Latex Condoms. On July 12, 1994, DRAERD issued the Testing Guidance for Non-Latex Male Condoms. This guidance provides necessary information for a non-latex condom and consists of the following parts: general information, detailed description of the material, manufacturing, material toxicity, finished product, quality assurance, packaging, shelf life, barrier properties/permeability, viral penetration study, clinical performance, and information for determining barrier properties of condoms to virus penetration.

Checklist for Sterile Lubricating Jelly. On July 19,1994, DRAERD issued its 510(k) checklist for sterile lubricating jelly used with transurethral surgical instruments. The purpose of this document is to outline the information necessary for manufacturers to provide in 510(k)s for these devices in order to permit a substantial equivalence determination.

Revision of Urodynamic/Uroflowmetry Systems. On July 29, 1994, DRAERD issued the revision of its February 1993 Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems. The purpose of this revision was to update the guidance based on current literature and to include ODE Tier 1 policy.

Conventional and Antimicrobial Foley Catheters. On September 12, 1994, DRAERD issued the Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters. The purpose of this guidance is to provide necessary information to manufacturers in order for them to be able to document substantial equivalence to a device in commercial distribution. Foley catheters are for single use, are intended for short-term (less than 30 days) use, and are retained in the bladder with a balloon inflated with a sterile liquid. This type of catheter is described in ASTM standard ASTM F 623-89. A catheter that is not within the scope of ASTM F 623-89 standard may merit special attention from the manufacturer as well as from FDA.

B. Reclassification/Classification of Devices

1. Reclassification of Classified Devices

On May 6, 1994, FDA published a notice of availability of the Preamendments Class III Devices Strategy Document in the *Federal Register*. The strategy document sets forth the agency's strategy for implementing section 515(i) of the Safe Medical Devices Act of 1990 (SMDA) which requires FDA to review the classification of premendments Class III (premarket approval) devices and either reclassify the devices into class I (general controls) or class II (special controls) or retain them in class III. The statute also requires FDA to establish a schedule for requiring the submission of premarket approval applications for those devices retained in class III.

In the light of the SMDA provisions and FDA resources, the 117 preamendments class III devices for which FDA has not initiated any action have been placed into three groups depending upon the potential for reclassification of the devices and their risk to public health. The strategy document currently being implemented identifies the groups, proposes SMDA activities achievable by December 1, 1995, and presents a schedule for those activities.

Other FY 94 activities concerning the reclassification of medical devices:

- Published a final rule in the *Federal Register* on October 4, 1994, announcing the reclassification of the Automated Heparin Analyzer from Class III to class II effective December 3, 1993.

- Published a proposed rule in the *Federal Register* on July 21, 1994, to exempt 164 Class I devices from premarket notification.

- The Ophthalmic Devices Panel, on October 28,1993, recommended reclassification of the Nd:YAG laser for iridotomy from class III to class II.

- The General Hospital and Personal Use Devices Panel, on May 11, 1994, recommended reclassification of the infant radiant warmer from class III to class II.

2. Classification of Unclassified Devices

- The Dental Panel, on June 29, 1994, recommended the classification of some bone filling and bone augmentation devices into class II and some into class III.

- The Orthopedic Device Panel, on July 22, 1994, recommended the classification of pedicle screws for degenerative spondylolisthesis and trauma into class II.

- The Radiology Devices Panel, on August 29, 1994, recommended the classification of picture archiving and communication devices (PACS): 3 devices into class II and 2 devices into class I exempt.

C. PMAs for Pre-Aamendments 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 that 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 fiscal 1994, as part of the implementation of the Pre-amendments Class III Strategy document, many proposed or final rules were drafted; these will be published in the Federal Register during fiscal 1995. The final published rules dealt with testicular prostheses and cranial electrotherapy

stimulators. The proposed rules cover the OTC denture cushion pad, the OTC denture repair kit, the endodontic heat sterilizer, and the implanted mechanical/hydraulic urinary contingence device.

D. Advisory Panel Activities

ODE held 23 panel meetings during FY 94 involving 24 meeting days. Each panel met at least once and some panels held several meetings. There were 13 formal training sessions held for new panel members. For career enhancement, ODE opened up the Executive Secretary function to new individuals with the skills and enthusiasm to do the job.

1. Diversity of Panel Membership

ODE Division Directors and Executive Secretaries, in addition to other review staff, diligently worked to meet diversity expectations of the Agency. They contacted current and former advisory panel members, members of professional societies, and medical colleges to solicit nominations for our panels. There are 148 total positions on the Medical Devices Advisory Committee, which is composed of 16 panels. From January 1, 1994, to September 19, 1994, female representation increased from 27 to 59 (an increase of 118%), and minority representation rose from 10 to 34 (an increase of 240%). Recruitment of members is a topic that has also been added to the formal training program that we give our executive secretaries and current panel members.

2. Interactive Review Process

A pilot interactive review of data among the sponsor, ODE staff, and selected panel members provided an innovative, efficient approach to the PMA and panel review processes. Future interactive reviews are being planned in an effort to get our staff and panel members more involved earlier in the review of PMA data.

3. Training for Executive Secretaries

ODE held approximately 10 meetings with our Executive Secretaries to keep them informed of new advisory committee policies, Task Force activities, diversity, and "lessons learned" from past panel meetings, and plans for upcoming meetings. All of our panels have executive secretaries in training or have newly trained executive secretaries representing the Agency at our meetings. The FDA Advisory Committee Exec Sec Go-Away at Airlie, Virginia, in June was well attended by CDRH Exec Secs and very informative. Each Executive Secretary participated in training on the new voice mail system and has access to current information about the respective panel on the Advisory Committee Information Line. See "Figure 1. FDA Advisory Committee Information Line", for further information.

4. Implementation of IOM Report

ODE continued to implement the recommendations identified in the Institute of Medicine's report titled "Food and Drug Administration Advisory Committees." The "CDRH Implementation Plan

for Advisory Committee Policies and Procedures" stipulates 12 action areas in response to the IOM Report. The action areas include procedures for filling specific panel vacancies, prescreening nominations, appointment of temporary voting members, scheduling meetings, responding to the press and public inquiries, developing questions for the panels, interactions with panel members, intellectual bias, annual reviews and updates for panels, and post-meeting feedback.

Annual Reviews/Updates by Panels. As required by our implementation plan, each of our panels met in closed session to be briefed on issues facing the respective division. ODE received an enormous amount of positive feedback on the closed sessions from our panel members. For ODE, a highlight of these sessions was that review staff from across the divisions had the opportunity to present their work to our panel members.

Agency Review of Recommendations. The ODE Director's Office is tracking recommendations made by the panels and division progress on those recommendations. A semi-annual report of outstanding issues is prepared for the Center Director. Also, at the start of each panel meeting, the Executive Secretary gives a status report on the progress that ODE made on the issues previously brought to panel. ODE also informs panel members of actions we have taken on an application (that has come to panel) prior to release of the information to the public.

E. ODE Integrity Program

1. Data Integrity

During FY 94, 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 internal inconsistencies within the submission, scientifically implausible data, contradictory information provided by scientific/clinical researchers, data inconsistent with the scientific/professional literature, information provided by employees of the applicant, and information obtained from legal documents.

This year saw the issuance of four letters to medical device firms 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 firms to whom the AIP letters were issued is suspended until the firms undertake an internal audit and implement an acceptable corrective action plan.

2. Program Integrity

During FY 94, more than 30 ethics issues and conflicts of interest problems arose. Several of these questions involved claims by manufacturers that they were not receiving fair or equal treat-

Figure 1. FDA Advisory Committee Information Line

The Food and Drug Administration (FDA) has implemented a telephone bulletin board to provide information about FDA advisory committees as soon as it becomes available. Many people who do not have immediate access to the Federal Register may find the Information Line a more convenient source for up-to-date information about FDA advisory committees.

For long distance callers only: 1-800-741-8138
Local callers, please use: 301-443-0572

When you call the FDA Advisory Committee Information Line, you will be able to hear general information about FDA advisory committees, and specific information about the committees and panels associated with any of the Centers with advisory committees in FDA. If you are only interested in the committees and panels associated with the Center for Devices and Radiological Health (CDRH), you can press 2 immediately. If you are only interested in a particular committee or panel, you can immediately press the number for that committee or panel and bypass all the general information.

Note: You must be at the FDA main menu to use the five-digit direct numbers. If you wish to check several committees/panels, press the five digit number for one committee/panel when the line is answered, listen to it, then press '9' for the FDA main menu, press the five-digit number for the next committee/panel of interest.

The CDRH advisory committees and panels and their five-digit numbers are:

Medical Devices Advisory Committee (by Panels)	Number
Anesthesiology and Respiratory Therapy Panel	12624
Circulatory System Panel	12625
Clinical Chemistry and Toxicology Panel	12514
Dental Products Panel	12518
Ear, Nose, and Throat Panel	12522
Gastroenterology and Urology Panel	12523
General and Plastic Surgery Panel	12519
General Hospital and Personal Use Panel	12520
Hematology and Pathology Panel	12515
Immunology Panel	12516
Microbiology Panel	12517
Neurological Panel	12513
Obstetrics and Gynecology Panel	12524
Ophthalmic Panel	12396
Orthopedic and Rehabilitation Panel	12521
Radiological Panel	12526
Other Medical Device Advisory Committees	
Device Good Manufacturing Practice Committee	12398
National Mammography Quality Assurance Committee	12397
Technical Electronic Product Radiation Safety Standards Committee	12399

ment during the review process. Other issues involved the receipt by ODE staff of free training, travel expenses, meals, and other things of value from manufacturers. Some questions involved the acceptance of faculty appointments and participation in professional associations.

F. Responding to Congressional Inquiries

Congressional interest in ODE programs continued to be strong during this fiscal year. Over the past year, ODE staff responded to 68 Congressional letters. Most inquiries related to device review times, informed consent, breast implants, pedicle screws, TMJ devices, or electrical muscle stimulators.

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 932 FOI requests during FY 94.

H. Publications

During FY 94, ODE staff authored three abstracts and four articles for publication in professional and scientific journals and made nine major presentations at professional, scientific, and trade association meetings.

V. SUPPORT ACTIVITIES

A. Recruitment and Hiring

In FY 94, in support of SMDA and the general product evaluation effort, the Office of Device Evaluation recruited and hired 104 scientific reviewers and support personnel. This included 85 scientific reviewers, 8 medical officers, and 11 support personnel. Thirty new hires (31%) were members of minority groups.

This enormous effort, developed and managed in ODE's Program Management Office, involved recruitment at other federal agencies, colleges and universities, industry groups and trade associations, as well as interactions within CDRH and with FDA personnel and EEO offices. In an effort to obtain highly qualified scientists, engineers, medical officers and other clinicians, recruitment packages, flyers, press clips, letters and personal contacts were used to publicize the availability of jobs in ODE. Also, PMO Staff attended several job fairs sponsored by the Lendman Group and Life Science Associates as representatives of the Office and Center.

An ODE Hiring Update Report was distributed bi-weekly to Office and Center management apprising them of ODE's hiring status and current and future staffing levels.

B. Staff Training

Extensive training continued to be a vital part of ODE's support activities in FY 94. Training included both in-house and off-site activities and took the form of workshops, seminars, informational exchange seminars, and structured courses at accredited educational institutions. Training for Center Advisory Panels is discussed in Subpart IV-D. above.

1. New Reviewer Training

ODE conducted new reviewer training classes in conjunction with the CDRH Staff College. These courses included an overview of the FD&C Act, with emphasis on 510(k), PMA and IDE sections of the law. In these classes, ODE reviewers received information on policies, procedures, practices and precedent decisions relevant to premarket submission evaluations. This year two new reviewer sessions were conducted. The first session was 8 weeks long with one 3-hour class per week. As a result of feedback from the first session, the second session lasted 9 weeks, with one 4-hour class per week. Over 150 new reviewers and employees looking for refresher training attended these classes in FY 94.

Because of the addition of many new reviewers in FY 94, ODE revived the ODE Mentor Program. New reviewers were assigned a "mentor" within their division to supplement the New Reviewer Training Program. This initiative allowed new reviewers to work with experienced ODE employees to become more quickly assimilated into the organization. In addition to the ODE Mentor Program, some divisions provided supplementary training to new reviewers in order

to focus on their distinct device areas. For example, in FY 94, DRAERD held two 3-hour 510(k) training sessions for all new reviewers. DCLD prepared a course in which new reviewers met with division experts for 4 hours a week to discuss device and administrative issues. DCRND also expanded the ODE Mentor Checklist to incorporate various division training.

ODE staff participated in numerous off-site training activities, in some instances to pursue higher level degrees, and in others to obtain specific coursework to address current needs. Additionally, ODE staff continued to attend professional meetings and workshops throughout FY 94: training and registration totaled $303,000; travel expenditures were almost $274,000.

2. Manager Training

- Branch Chief Meetings. Monthly Branch Chief meetings were held during FY 94 to discuss current management issues.
- EEO Training. All managers and supervisors within ODE attended a two-day workshop on matters relative to non-discrimination in the workplace.
- Supervisory RAPID Training. ODE managers attended a "Recruit and Promote Individuals with Disabilities" workshop. This training fostered the hiring and advancement of individuals with disabilities.
- AIDS Training. All ODE supervisors attended a workshop on issues regarding HIV infected employees in the workplace.

3. Workshops and Seminars

Several workshops were sponsored and held either on-site or in the Washington Metropolitan Area to furnish new training and information to the ODE workforce. These workshops and seminars are examples of ODE's effort to keep our employees in the forefront of current medical device and public health issues.

Workshops and seminars conducted in-house included:

- Concepts and Practices in the Evaluation of Laboratory Methods. This workshop was sponsored by ODE's Division of Clinical and Laboratory Devices.
- Pathology of Cardiovascular Disease. This lecture series, sponsored by ODE's Division of Cardiovascular, Respiratory and Neurological Devices, included 4 workshops.
- Microbiology and Engineering of Sterilization Processes. This 3-day workshop, given by Dr. Irving Pflug, Department of Food Science and Nutrition, University of Minnesota, highlighted the understanding of numerous medical device sterilization procedures.

- Myers-Briggs Type Indicator. This training, provided for the Division of Ophthalmic Devices, included the completion of the Myers-Briggs pretest as well as an in-depth evaluation of the results.

- Write-it-Right. ODE sponsored two Write-it-Right seminars in FY 94 which covered writing techniques in relation to the review process.

Additional Workshops and Seminars Conducted in the Washington Metropolitan Area included:

- Reuse of Dialysis Equipment. This one-day public workshop was held for the presentation and discussion of a draft guidance document for premarket testing and labeling for hemodialyzers for reuse.

- Policy Conference on Clinical Investigation of Antiarrhythmic Devices. A policy statement was developed during this two-day workshop that addresses the types of clinical evaluation necessary for commercial release and subsequent assessment of antiarrhythmic devices. This statement is consensus-based, derived from a wide spectrum of expert opinion including physicians and other health professionals constituting a joint Task Force representing the following professional organizations: North American Society of Pacing and Electrophysiology (NASPE), American College of Cardiology, American Heart Association, and the Working Groups on Arrhythmias and Pacing of the European Society of Cardiology.

4. CDRH Informational Exchange Seminars

ODE participated in numerous informational exchange seminars with other offices within CDRH in FY 94, such as ODE participation in the CDRH Scientific Roundtables and OSB Safety Conferences.

5. ODE Vendor Day

On February 4, 1994, ODE sponsored its first "Vendor Day" with endoscopic device manufacturers. This 4-hour information exchange included demonstrations of endoscopic materials and techniques from several manufacturers. Vendor Day allowed ODE reviewers to gain knowledge and hands-on experience concerning endoscopy equipment. This was the first of several planned scientific exchanges with industry.

C. Office Automation

In spite of the rapid increase in staff during FY 94, ODE managed to provide computer equipment to all new ODE employees and to significantly upgrade its existing base of equipment. Use of the IMAGE system by ODE reviewers increased and they had access to an ever-increasing number of documents. Progress continued in the conversion of ODE tracking systems to the Oracle database

management system. The Division of Small Manufacturers Assistance (DSMA), located within our sister Office of Health and Industry Programs, again used the data from various ODE tracking systems to provide status information to sponsors of device applications. FY 94 proved to be a year of significant expenditures for equipment and software to enable reviewers to more efficiently perform necessary review activities.

1. Tracking Systems

The CDRH Office of Information Systems (OIS) continued to provide systems analysis, design, development and programming support to ODE for its document tracking systems. These systems include the ODE Division Tracking System, the Pre-Market Approval Tracking System, the 510(k) Tracking System, the IDE Tracking System, and the Device Master Files.

The ODE Program Management Office (PMO) conducted a study of the present division tracking system and met with ODE managers and staff. These individuals expressed their views on the weaknesses and strengths of the current system and identified the information needed from a division tracking system. OIS utilized the results of the ODE study and held follow-up meetings with representatives of the ODE divisions. These efforts formed the basis for design of the division tracking system scheduled for completion in Spring 1995.

ODE and OIS representatives participated in extensive discussions on redesign of the PMA Tracking System. Completion and implementation of the new system is scheduled for Spring 1995.

OIS made several modifications to the 510(k) tracking system. The changes included integrating the system with the Tier Review process, providing for the capture of CLIA categorization codes, completing the mechanism for loading data on the Electronic Docket, and developing reports to track rescissions, appeals and interaction with Center components outside ODE.

ODE decided to reactivate the use of the Device Master File tracking system. After OIS modified the data entry system and provided training, ODE began entering device master file records from hand logs. ODE then inventoried and prepared master files for scanning into the IMAGE system. The ODE document mail center contractor now performs this task.

2. Document Imaging

ODE continued to use the Center's optical storage and retrieval system (IMAGE) in FY 94 to access completed device applications from 1976 to the present. Other Offices within CDRH used IMAGE to access documents for collaborative reviews, for field investigations, and to answer FOI requests. FOI requests were satisfied by printing 510(k) summaries from the IMAGE system.

This year the use of the IMAGE system increased for a number of reasons. The increased ODE staff created a larger base of people needing access to documents on IMAGE. In FY 93, 186

users accessed the system and in FY 94, 306 users accessed the system. Additional documents were scanned to IMAGE in FY94. IDE scanning became routine and device master file scanning began (see Figure 2). Finally, access to IMAGE expanded with the installation of new PCs. PC users received software to access IMAGE from the PC on their desk; when the installation of new PCs is complete, over 100 ODE PC users will have IMAGE access from their desk.

ODE continued scanning PMA originals upon receipt. PMA amendments and supplements related to scanned originals were also scanned on arrival. On-arrival scanning will expand to cover 510(k)s and IDEs, but no date has been set for this scanning.

Figure 2. Cumulative Number of ODE Documents Scanned into IMAGE Through FY 94.

Document Type	Cumulative Total
510(k)	40,186
PMA Original	406
PMA Supplement	1475
IDE	701
Master File	354

3. Electronic Submissions

The ODE Division of Ophthalmic Devices (DOD) has received electronic submissions for original IDEs and new protocols for devices used in refractive eye surgery. These submissions have demonstrated significant benefits for the review of these devices. The review time decreased from 3 days to 1 day, since retyping was eliminated and text from the sponsor's diskette could be copied into the final review document.

In addition, the use of this process identified formatting issues related to document translation that could be applied to future PMA submissions. Documents translated to WordPerfect 5.1, ODE's standard wordprocessing software, can present problems with tabs, margins, pagination and font selection. Other sources of potential problems are the submission of spreadsheet data

and documents in a compressed format. Knowledge of these issues will save both the reviewer and the device sponsor time on future submissions.

The ODE Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND) conducted an electronic submission pilot project for two PMA supplements. As with the DOD electronic submission, the pilot uncovered formatting issues related to document translation. Due to the graphics in one submission, the reviewer decided to use WP 5.2 for Windows since WP 5.1 viewing was not acceptable. While this choice improved viewing and ease-of-use, problems arose in transmitting the final document to the sponsor. With the second supplement, formatting and printing problems caused the reviewer to perform a typical review from the hard copy.

Regardless of these difficulties, the pilot demonstrated that electronic review is feasible. Having a copy of the submission on diskette minimized the need to scan a document into WordPerfect format in lieu of retyping. DCRND will continue to pilot electronic submissions in FY 95 and will use an alternative software platform, Adobe Acobat. This platform allows the manufacturer to create a document in any software and then save the document as a postscript text file which can be read with the Acobat Reader or Exchange.

ODE will continue to pilot electronic submissions. Other divisions within ODE will pilot electronic submissions using different software packages. The pilot program will expand in FY 95 to include 510(k)s.

4. DSMA 510(K) Status Reporting System

DSMA continued to access the ODE tracking system to provide status information to sponsors of device applications. This action has resulted in fewer calls to ODE for the status of 510(k) applications, allowing reviewers more time to devote to review activities.

5. User Support

The ODE PMO continued to provide computer support to more than 360 people within the Office. This support involved the provision of computer equipment, repairing/arranging for maintenance on equipment, purchasing/installing software, printer installation and maintenance, answering questions related to software packages, and purchasing furniture and supplies needed for day-to-day operations. To assist with this effort, ODE expanded the use of division focal points to assist users within each ODE division. Additional focal points were chosen and formal meetings were held. ODE plans to further expand this concept to provide more rapid response to a users' need for assistance.

6. ODE Local Area Network (LAN)

ODE continued to add new users to its local area network. The ODE LAN serves as the major print facility for PC users. Networked laser printers are available to all PCs on the network. ODE added 2 printers to the ODE LAN and improved LAN printing by changing the method of

access to some LAN printers.

The LAN served another useful purpose by maintaining a link with the Division of Clinical Laboratory Devices (DCLD) when the division moved to a separate building in June 1994. Using the Center Ethernet system, the ODE LAN provided printing for DCLD PC users and access to the LAN server for ODE boilerplate letters that are routinely updated.

7. DCLD Moves to a New Location

As mentioned under the section on ODE LAN, ODE conducted the move of the Division of Clinical Laboratory Devices to its new location. This effort involved disassembly and assembly of computer equipment and the installation of VAX printers, LAN printers, and facsimile machines. Due to planning, hard work and the fact that only one division moved, DCLD PCs were operational within a few days.

8. Software Conversion

With the Center moving to a new communication software standard, ODE began the installation of the new communication software (Smarterm) on ODE PCs. Additional work remains to effect a complete conversion.

Another conversion began as ODE moved from the Direct Access menu system to the use of Windows as a means to launch applications. This effort involved the development of a standard Windows installation for new PC installations. In addition, ODE developed a standard PC setup for new installations. This involves the WordPerfect 5.1 directory structure, the Windows screens, and the use of DOS 6.21..

9. Training

With the increase in employees, training in the use of ODE systems became a high priority. Therefore, the Program Management Office served as a liaison between ODE and the Office of Information Systems (OIS) to schedule ODE users for OIS sponsored training classes until OIS established a person as the Registrar. This effort involved receiving training requests from ODE employees, checking the class roster for available space, and sending training requests to OIS. It also involved maintaining waiting lists for the next available class and also requesting special classes for ODE. As part of the training effort, a new-employee training form and a new-employee status checklist were developed. This effort lasted from January 1994 through July 1994.

10. ODE Property Inventory

ODE established an inventory control system for computer equipment and PC software, using Paradox 4.5 for Windows. This program captures information on individuals, equipment, network cards, and software. Using information gathered by this program, ODE will plan for the conversion to Windows and IMAGE on all PCs.

11. ODE Document Mail Center Contract

The PMO and POS Staffs participated in a CDRH working group during FY 94 for the purpose of selecting a contractor to operate the ODE document mail center, the Office of Compliance document mail center and the CDRH mail room. This group interviewed bidders, evaluated proposals and chose the contractor to assume the operation of the mail centers and mail room. The PMO computer support group provided the necessary computer equipment and computer support to the document mail center. The POS staff developed an information package for the contractor employees, coordinated all contractor training, and developed a training manual for the ODE document center contractor. ODE now serves as the Project Officer for this entire contract.

12. Equipment/Software/Supplies

The ODE expenditure for this category for FY94 was $466,000. Major Equipment Purchases were:

- 57 AST 486/66d PCs
- 7 AST 486/33 PCs
- 5 Canon plain paper facsimile machines
- 12 Hewlett Packard 4 Plus laser printers
- 5 Hewlett Packard 4M Plus laser printers
- 2 Hewlett Packard 4SIMX laser printers
- 4 Hewlett Packard Scanjet IIP
- 1 Overhead PC Projection Pad
- 5 Talaris 1794 laser printers
- 1 Polaroid CI5000s digital film recorder

Additionally, with Center funding, ODE obtained equipment to allow access to the Center's IMAGE system. This equipment included 34 AST 486/66d PCs and upgraded monitors, graphics cards, and hard disk drives for existing PCs.

ODE used FY 94 funds to upgrade some of the major software packages used within ODE. ODE purchased Central Point Anti-Virus 9.0 for Windows, Smarterm 320 for DOS and Smarterm 420 for Windows, Microsoft DOS 6.0/6.2, Harvard Graphics 3.0 for DOS, Lotus 1-2-3 v. 3.4 and 4.0, DBASE IV v. 2.0 and DBASE 5 for DOS, and WordPerfect 5.2 and 6.0 for Windows. In addition, ODE purchased Microsoft Project 4.0 for Windows and DEC Pathworks client licenses.

With Center funding, ODE obtained client licenses for the DEC Pathworks LAN running on the Center's VAX computer, Smarterm software to access the VAX, and DOS 6.0 upgrades.

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 90 - FY 94

Type of Submission	No. Received				
	FY 90	FY 91	FY 92	FY 93	FY94
Premarket Approval					
Original Applications	79	75	65	40	43
Amendments	569	680	740	665	704
Supplements	660	593	606	395	372
Amendments to Supplements	1,069	954	897	782	788
Reports for Orig. Applications	479	441	483	442	407
Reports for Supplements	22	15	21	17	12
Master Files	37	42	41	71	130
PMA Subtotal	2,915	2,800	2,853	2,412	2,456
Investigational Device Exemptions					
Original Appplications	252	213	229	241	171
Amendments	288	283	297	320	253
Supplements	3,043	3,647	3,644	3,668	3,020
IDE Subtotal	3,602	4,152	4,170	4,229	3,444
Premarket Notification					
Original Notifications	5,831	5,770	6,509	6,288	6,434
Supplements	3,752	3,917	4,555	3,940	4,571
510(k) Subtotal	9,362	9,687	11,064	10,228	11,005
PMA/IDE/510(k) Total	15,879	16,639	18,086	16,869	16,905

Table 2. Original PMAs
FY 90 - FY 94

Action	FY 90	FY 91	FY 92	FY 93	FY94
Number received	79	75	65	40	43
PMA Actions					
Filing Decisions					
Filed (%)	53(52)	52(50)	46(54)	33(62)	38(60)
Not Filed (%)	49(48)	42(40)	28(33)	16(30)	25(40)
Others(%)	N/A	10(10)	11(13)	4 (8)	0(0)
Filing Decision Subtotal	102	104	85	53	63
Review Activities					
Major Deficiencies	33	28	31	21	30
Minor Deficiencies	2	5	5	10	4
Other[a]	67	127	162	171	191
Review Activity Subtotal	102	160	198	202	225
Approval Decisions					
Approvals(%)	47(42)	27(27)	12(24)	24(35)	26(39)
Approvable(%)	45(41)	46(46)	18(37)	23(34)	22(33)
Not Approvable(%)	19(17)	27(27)	15(31)	21(31)	18(27)
Denials	0 (0)	0 (0)	4 (8)	0 (0)	0(0)
Approval Decision Subtotal	111	100	49	68	66
Total PMA Actions	315	364	332	323	354
Average review time (days) for approvals[b]					
FDA	228	199	146	328	374
Non-FDA	42	87	40	109	78
Total	283	285	186	437	452
Average elapsed time (days) for approvals[c]					
FDA	302	335	236	547	649
Non-FDA	113	298	74	252	174
Total	415	633	310	799	823
Number under review at end of period[d]					
Active[e]	44	49	87	94	67
(Active and overdue)	(5)	(2)	(36)	(45)	(22)
On hold[f]	72	86	77	56	72
Total	116	135	164	150	139

a/ Includes actions that did not result in an approval/denial decision, such as GMP deficiency letters prior to inspection, an applicant directed hold, reclassification of the device and conversion of the PMA to another regulatory category, or official correspondence concerning the abandonment or withdrawal of the PMA, placing the PMA on hold, and other

(Continued on next page.)

Table 2. Original PMAs
FY 90 - FY 94

(Continued from previous page.)

miscellaneous administrative actions.

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 FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock.

c/ The average elapsed time includes all increments of time a PMA was under review, including all the increments of time it was under review by FDA and all increments of time it was on hold. Thus, average elapsed time, unlike average review time, *includes* all increments of time that transpired from the filing date until approval or denial. Under average elapsed time, the review clock is not reset upon the receipt of a "major 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 not reflected in the table.

e/ FDA responsible for processing application.

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

Table 3. PMA Supplements
FY 90 - FY 94

Action	FY 90	FY 91	FY 92	FY 93	FY94
Number received	660	593	606	395	372
PMA Supplement Actions					
Panel Track Filing decisions[a]					
Filed(%)	6(35)	5(38)	4(27)	1 (10)	3(60)
Not Filed(%)	11(65)	8(62)	11(73)	6 (90)	2(40)
Other(%)	N/A	0 (0)	0 (0)	0 (0)	0 (0)
Filing Decision Subtotal	17	13	15	7	5
Review Activities[a]					
Major Deficiencies	30	14	2	5	1
Minor Deficiencies	0	0	0	0	0
Other[b]	292	251	196	251	219
Review Activities Subtotal	322	265	198	256	220
Approval Decisions					
Panel track approvals(%)[c]	5 (1)	2 (1)	1 (1)	2 (1)	3(1)
Nonpanel track approvals(%)	695(76)	478(64)	393(62)	352(62)	382(65)
Approvable(%)	138(15)	138(18)	120(18)	91(16)	95(16)
Not approvable(%)	87 (9)	134(18)	122(19)	124(21)	104(18)
Approval Decision Subtotal	919	752	636	569	584
Total PMA Supplement Actions	1,258	1,030	849	832	809
Average review time(days) for approvals[d]					
FDA	133	111	113	168	253
Non-FDA	26	32	22	35	42
Total	159	143	135	203	295
Average elapsed time(days) for approvals[e]					
FDA	146	131	135	213	301
Non-FDA	35	44	32	56	70
Total	180	175	167	269	371
Number under review at end of period[f]					
Active[g]	215	206	341	346	243
(Active and overdue)	(7)	(1)	(98)	(173)	(110)
On hold[h]	120	133	144	119	133
Total	335	339	485	465	376

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.

(Continued on next page.)

Table 3. PMA Supplements
FY 90 - FY 94

(Continued from previous page.)

b/ Includes actions that did not result in an approval/denial decision, such as GMP letters prior to inspection, an applicant 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 are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock.

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. Thus, average elapsed time, unlike average review time, *includes* all increments of time that transpired from the filing date until approval or denial. Under average elapsed time, the review clock is not reset upon the receipt of a "major amendment".

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 90 - FY 94

Action	FY 90	FY 91	FY 92	FY 93	FY 94
Number received	252	213	229	241	171
Number of decisions					
Approved(%)	95(38)	72(33)	68(32)	60(24)	47(27)
Not approved (%)	146(59)	141(64)	130(60)	166(67)	109(63)
Other (%)[a]	7 (3)	7 (3)	17 (8)	22 (9)	18(10)
Total	248	220	215	248	174
Average FDA review time (days)	29	29	30	28	29
Percent (%) of decisions made within 30 days	99	99	97	97	95
Number under review at end of period[b]	20	12	21	14	11
Number overdue at end of period	0	1	0	3	0

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.

Table 5. IDE Amendments
FY 90 - FY 94

Action	FY 90	FY 91	FY 92	FY 93	FY 94
Amendments received[a]	288	283	297	320	254
Decisions on Amendments					
Approved(%)	123(46)	133(46)	127(43)	93(29)	109(43)
Not approved (%)	79(29)	80(28)	92(31)	131(40)	68(27)
Other (%)[b]	68(25)	74(26)	78(26)	100(31)	77(30)
Total	270	287	297	324	256
Average FDA review time (days)	24	23	24	25	24
Percent (%) of decisions made within 30 days	99	99	99	96	97
Average approval time (Days) for IDEs with Amendments					
FDA time	73	71	79	83	83
Non-FDA time	114	118	109	129	159
Total time[c]	187	189	188	212	242
Number of Amendments per Approved IDE	1.8	1.8	N/A	2.2	2.3
Amendments under review at end of period[d]	29	25	21	16	11
Amendments overdue at end of period	0	0	1	2	0

a/ Includes only those submissions 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 the date the original IDE was received to the date of 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.

Table 6. IDE Supplements
FY 90 - FY 94

Action	FY 90	FY 91	FY 92	FY 93	FY 94
Number received	3,043	3,647	3,644	3,668	3,020
Number of decisions	2,968	3,705	3,469	3,814	3,070
Average FDA review time (days)	22	21	23	24	23
Percent (%) of decisions made within 30 days	99	99	99	97	98
Number under review at end of period[a]	245	189	359	213	160
Number overdue at end of period	0	0	4	8	1

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.

Table 7. 510(k)s
FY 90 - FY 94

Action	FY 90	FY 91	FY 92	FY 93	FY 94
Number received	5,831	5,770	6,509	6,288	6,434
Number of decisions					
Substantially equivalent	4,748	4,294	3,776	4,007	5,498
Not substantially equivalent	117	122	130	135	135
Other[a]	1,332	951	956	931	1502
Total	6,197	5,367	4,862	5,073	7,135
Percent(%) not substantially					
Equivalent[b]	2.4	2.8	3.3	3.3	2.4
Average review time (days)					
FDA time[c]	78	81	102	162	184
Total time[d]	98	102	126	195	216
Median review time (days)					
FDA time[c]	71	73	88	144	134
Total time[d]	78	82	90	164	155
Percent (%) of decisions made within 90 days, based on					
FDA time[e]	100[i]	100[i]	94	46	45
Total time[d]	57	57	45	20	27
Number under review at end of period[f]					
Active[g]	1,174	1,402	2,599	3,822	2,414
(Active and overdue)	0	0	(331)	(1894)	(460)
On hold[h]	726	889	1,352	1,335	1,960
Total	1,900	2,291	3,951	5,157	4,374

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 time includes all increments of time FDA reviewed a 510(k), so long as the 510(k) document number did not change; changes in 510(k) document numbers occur rarely.

d/ Includes all time from receipt to final decision, i.e., does not exclude time 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/ 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 decisions) because of deletions and conversions which are not reflected in the table.

g/ FDA responsible for processing notification.

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

i/ 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 84 - FY 94

Type of Submission	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994
Orig. PMAs	65	97	69	81	96	84	79	75	65	40	43
PMA Supp.	435	393	478	700	727	810	660	593	606	395	372
Orig. IDEs	203	204	206	218	268	241	252	213	229	241	171
IDE Amend.	N/A	N/A	365	265	316	271	288	283	297	320	254
IDE Supp.	3,077	2,457	2,884	2,836	3,391	3,038	3,043	3,647	3,644	3,668	3,020
510(k)s	5,004	5,254	5,063	5,265	5,536	7,022	5,831	5,770	6,509	6,288	6,434
Total	8,784	8,974	8,974	9,365	10,334	11,466	10,153	10,581	11,350	10,952	10,293

Table 9. Major Submissions Completed
FY 84 - FY 94

Type of Submission	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994
Orig. PMAs	43	37	72	46	46	56	47	27	12	24	26
PMA Supp.	243	377	477	565	652	519	700	479	394	354	385
Orig. IDEs	198	201	213	224	260	245	248	220	215	248	174
IDE Amend.	N/A	361	330	253	327	280	270	287	297	324	256
IDE Supp.	N/A	2,190	3,599	2,784	3,405	3,023	2,968	3,705	3,469	3,814	3,070
510(k)s	4,262	5,095	5,359	4,992	5,513	6,136	6,197	5,367	4,862	5,073	7,135
Total	4,746	8,261	10,050	8,864	10,203	10,259	10,430	10,085	9,249	9,837	11,045

N/A - Not available.

Appendix A. ODE Staff Roster
Fiscal Year 1994

Office of the Director

Acker, Rita
Alpert, Susan
DeMarco, Carl
Gornick, MaryAnn
Grygier, Debbie
Hobbs, Cathy
Phillips, Phillip
Pluhowski, Nancy
West, Dave

Program Management Office

Abernethy, Scott
Appler, Kathryn
Broughton, Shirley
Chesmore, Kaye
Clingerman, Angie
Dowtin, Lesa
McGeehan, Rob
Moran, Shelly
Nairn, Beth
Jaeger, Jeffrey
Robins, Lisa
Trammell, Dan
Wedlock, Chuck
Wright, Mark

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

Division of General and Restorative Devices

Barrett, Suzanna
Basu, Sankar
Benninger, Paul
Berne, Bernie
Bolden, Brenda
Brower, Anita
Browne, Myra
Bryant, Joanne
Budd, Roger
Clark, Tracey
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

Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

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

Appendix B. ODE Organization Chart