December 15, 1989

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

SUBJECT: Office of Device Evaluation Annual Report for Fiscal Year 1989

TO: Director and Acting Deputy Director,
Center for Devices and Radiological Health

I am pleased to present to you the ODE Annual Report for Fiscal Year 1989. As you will see in the report, some significant accomplishments were achieved during the past year. We approved 56 PMAs, the second highest number of PMAs ever approved in a fiscal year. For the first time in our history, all original IDE decisions and 99% of all IDE amendments and supplements were made within the 30 day statutory time frame. Similarly, 99% of the 510(k) decisions were made within 90 days. To help enhance the quality of both submissions and the review process, we developed 24 guidance documents in the past year. All this was accomplished despite our having significantly fewer FTEs available in FY 89 than in FY 88 and a 15% and 12% increase, respectively, for total submissions and major submissions. One area in which reduced resources had a negative effect was in the PMA program. We ended FY 89 with an increased number of PMAs and PMA supplements active and overdue. This area will be given special attention this year.

ODE's achievements were possible because of the hard work and dedication of our staff plus the support we received from other Center offices. On behalf of the ODE staff, I want to thank you and other CDRH offices for your support and help during the past year.

Robert L. Sheridan

Robert L. Sheridan

OFFICE OF DEVICE EVALUATION

ANNUAL REPORT

FISCAL YEAR 1989

Center for Devices and Radiological Health
Food and Drug Administration

Acknowledgements

The Office of Health Affairs, CDRH, provided valuable assistance by reviewing this report. Carl T. DeMarco compiled and edited the report. The PMA, IDE, and 510(k) staff offices provided the data and each ODE division provided the specific divisional information used in the report. Leslie E. Dorsey provided data input support using desktop computer equipment and software.

OFFICE OF DEVICE EVALUATION
ANNUAL REPORT
Fiscal Year 1989

Dear ODE Colleague:

We are especially pleased to present to you the ODE Annual Report for Fiscal Year 1989. Your accomplishments were remarkable considering the strain of shrinking resources, time lost in the office move, and the record setting numbers of submissions we received. You've earned the right to feel a sense of professional pride and satisfaction.

You will notice some major changes in this year's report. Some of them, like the inclusion of divisional statistics, were started in the midyear report. The Annual Report, however, goes much further and incorporates a "State of the Division" report for each ODE division. These reports highlight the exciting things that are going on in the divisions. You will also find new statistical information dealing with IDE amendments and how long it takes to approve an IDE after an initial disapproval.

We wish to thank each of your personally for your support during the past year. Without your cooperation, dedication, and hard work, ODE could not lay claim to the accomplishments that are set forth in this report.

Robert L. Sheridan
Director

David L. West
Acting Deputy Director

Jerome A. Donlon
Associate Director

Abhijit Acharya
Director, Division of Cardiovascular Devices

Kathryn K. Appler
Director, Program Management Office

Halyna P. Breslawec
Director, Division of Gastroenterology, Urology and General Use Devices

Thomas M. Tsakeris
Acting Director, Division of Clinical Laboratory Devices

Carl A. Larson
Director, Division of Surgical and Rehabilitation Devices

Richard E. Lippman
Director, Division of Ophthalmic Devices

George C. Murray
Director, Division of Anesthesiology, Neurology and Radiology Devices

Philip J. Phillips
Director, Program Operations Staff

Lillian L. Yin
Director, Division of Obstetrics, Gynecology, Ear, Nose, Throat and Dental Devices

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EXECUTIVE SUMMARY

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FISCAL YEAR 1989

The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research or marketing. The following are the highlights of the activities of ODE for fiscal year 1989 (FY 89), beginning on October 1, 1988 and running through September 30, 1989. These highlights are explained more fully in the body of the report.

Workload

- ODE experienced an increase in total incoming submissions during FY 89. We received a record setting 17,635 total submissions for the year which represents an increase of 2,277 documents, or a 15% increase over FY 88.

- We also received a record number of major submissions: PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s. The major submissions received rose from 10,018 in FY 88 to 11,195 in FY 89, an increase of 1,177 major submissions or 12%.

- Among the major submissions received, there was an unusually high number of 510(k) submissions for examination gloves because of our regulatory activities in the AIDS area. Similarly, we received an onrush of original and supplemental PMAs for IOLs. The filing of these PMA

documents by the end of December 1988 enabled the sponsors of IOL studies to continue their adjunct studies.

Resources

- During this past fiscal year we suffered serious losses in ODE staffing. Over the past several years, ODE had an increasing number of "Full Time Equivalents" (FTEs) allocated to its programs. In addition to these increases in ODE's ceiling, during FY 87-89, we were permitted to hire over ceiling based on underutilization elsewhere in FDA. Because of the recent scarcity of resources throughout the Agency, however, we now need to comply with official allocations. As a result, ODE's usage of FTEs dropped from about 230 FTEs in FY 88 to 222 in FY 89.

- Also, during this fiscal year, ODE moved its offices from Silver Spring to Rockville resulting in the loss of 18 calendar days or 13 work days. This is equivalent to losing about 14 staff members for the year. In addition to the virtual loss of 14 FTEs during that 18 day period, time before and after the move also was lost due to packing, unpacking, lost files and furniture, inoperative and inaccurate telephoning, imbalance in air-conditioning, a subpar electrical supply, etc. Although there will be long term benefits to be derived from the move, it constituted a serious negative impact on our operations during FY 89.

- Despite these setbacks of more than 20 total FTEs and the increases in our workload, we were still able to achieve an exceptional level of performance as documented in this report.

Premarket Approval

- ODE received 84 original PMAs during FY 89. We approved 56 PMAs this year, which represents the second highest number of PMAs ever approved in a fiscal year. This is one of our more noteworthy accomplishments this year, even when compared to the 72 PMAs, the all-time high, approved in FY 86, when we look at three operating factors. First, the sheer volume of incoming documents stretched our system to its limits. Second, the large number of incoming PMAs required a significant amount of time for analysis and decision making concerning their filing status. Third, most of the current PMA applications are for "new-technology" devices that require more care in the evaluation of their safety and effectiveness. These difficult circumstances did not exist in FY 86.

- The total number of pending applications and those active and overdue for both PMAs and PMA supplements rose somewhat over last year. This was due in large part to the large numbers of IOL applications received just before the end of calendar year 1988. For example, 53 of the 86 total overdue applications at the end of this fiscal year for both PMAs and PMA supplements are for IOLs. We are working hard to reduce the overall inventory and backlog of PMAs and PMA supplements and, in response to the extraordinary IOL activity, we set up an IOL Strike Force to work on these applications until they are cleared up.

- The average review time for original PMAs was reduced for the third consecutive year, from 262 days in FY 88 to 247 days in FY 89. Average review time for PMA supplements also was reduced from 124 days in FY 88 to 122 in FY 89, continuing a four year trend.

Investigational Devices

- There were no original IDEs, IDE amendments, or IDE supplements active and overdue as of the close of business for FY 89. All original IDEs (100%) were reviewed within 30 days. This is the first time this has ever happened in any ODE program area. Ninety-nine percent (99%) of IDE amendments and IDE supplements were reviewed within 30 days.

Premarket Notification (510(k))

- There were no active and overdue 510(k)s as of the end of FY 89. Average FDA review time for 510(k)s rose somewhat to 66 days in FY 89 from 64 days in FY 88. The percentage of 510(k)s reviewed within the 90 day statutory period remained constant at 99%.

Guidance for Industry and Reviewers

ODE and its divisions developed 24 new guidance documents for use by industry and ODE reviewers:

- Premarket Notification - Consistency of Reviews
- Review of IDEs for Feasibility Studies
- 510(k) Sign-Off Procedures (Revised)
- Telephone Notification for 510(k)s Under Review for 75 Days or Greater
- Training for ODE Employees
- Toxicology Risk Assessment Committee
- Contact Lens Testing Guidance
- Salt Tablet Labeling

- Salt Tablet Safety Alert
- Definition of Disposable Contact Lenses
- 7-day Extended Wear Contact Lenses
- Review of UV Absorbing Posterior Intraocular Lenses
- Waiver of Prior Notification and Approval for Minor Tier A Changes in IOLs
- Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter Guidance
- Laser Catheter Guidance
- Valvuloplasty Guidance
- Vascular Graft Guidance
- Intraaortic Balloon Pump Guidance
- Pacemaker Test Guidance
- Programmer Module Guidance
- Revised Conditions of Approval for Pacemakers
- Fetal Doppler Ultrasound
- PMA Guidance for Endosseous Implants for Prosthetic Attachment
- Examination Glove 510(k)s

Classification of Medical Devices

- During the year, FDA proposed the classification of 70 electromedical devices into class I.

Reclassification

- During the year, the $PcCO_2$ monitor, the ceramic hip prosthesis and the poly(glycolide/L-lactide) surgical suture were reclassified from class III to class II.

- We published in the Federal Register a proposal to reclassify the automated differential cell counter from class III to class II.

- Our advisory panels recommended that the nonabsorbable poly(ethylene terephthalate), polypropylene and silk surgical sutures, the porous-coated hip prosthesis, and the suction lipectomy system be reclassified from class III to class II.

- We filed a petition to reclassify the Argon laser for rhinology and laryngology from class III to class II.

Call for PMAs for Pre-Amendments Devices

- This year we published a final rule requiring a PMA for the implanted intracerebral/subcortical stimulator for pain relief.

- We published a notice of advanced rulemaking to issue 515(b) regulations for an additional 31 class III pre-Amendments devices having a high priority for the application of PMA requirements.

Exemptions from Premarket Notification

- During FY 89, we exempted the following class I devices from premarket notification requirements:

  General and Plastic Surgery devices - 8
  Radiology devices - 4
  Dental devices - 22
  Hematology and Pathology devices - 24

Immunology and Microbiology devices - 37
Anesthesiology devices - 13
Cardiovascular devices - 3
Gastroenterology-Urology devices - 9
General Hospital and Personal Use devices - 6
Neurology devices - 7
Obstetrics and Gynecology devices - 3
Physical Medicine devices - 2

Panel Activities

- We conducted 32 advisory Panel meetings during the year.

Freedom of Information Requests

- ODE processed a record 1,500 Freedom of Information requests.

Automation and Communication

- Major activities in office automation included the continued procurement and installation of hardware and software, the modification of the application tracking system, training of users, and improvement of telecommunication capabilities. Also, we installed fascimile machines and joined the FDA voice mail system.

ANNUAL REPORT

OFFICE OF DEVICE EVALUATION

FISCAL YEAR 1989

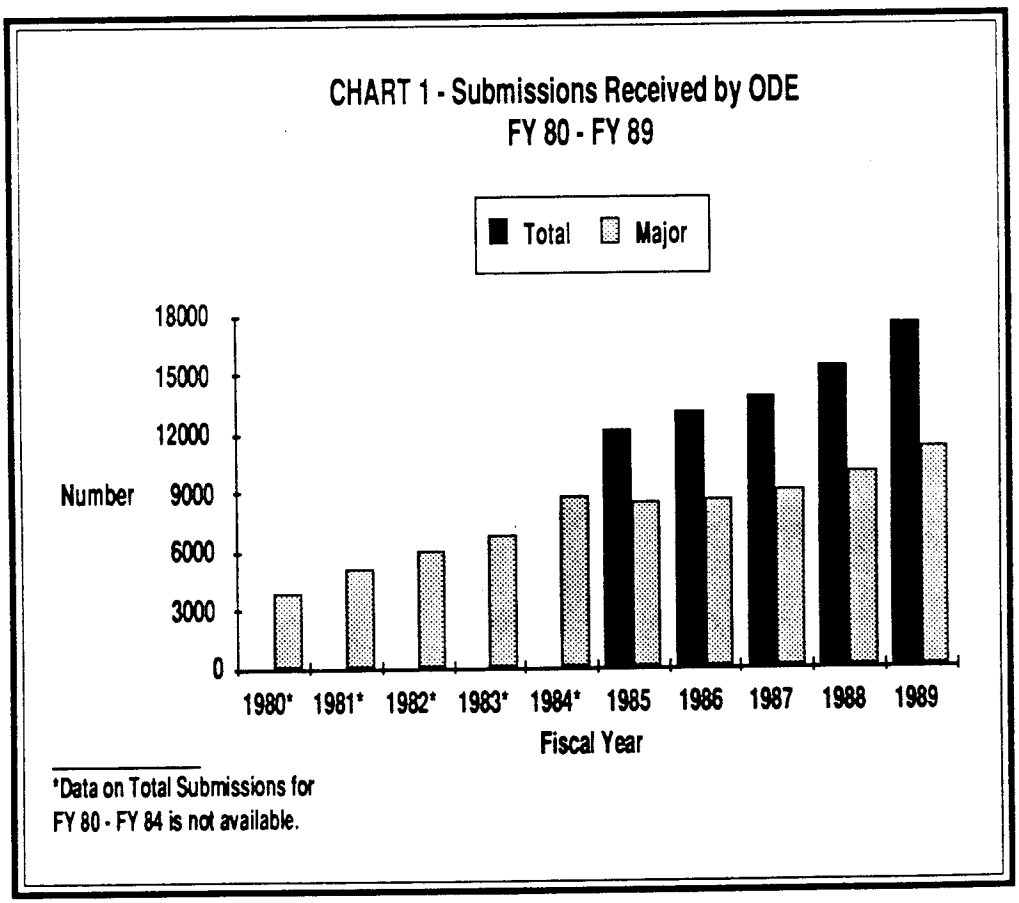
I. INTRODUCTION

The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research or marketing. This report provides information about major programs administered by ODE during Fiscal Year 1989 (FY 89), beginning on October 1, 1988 and running through September 30, 1989. The report emphasizes activities of the premarket approval, investigational device exemption, and premarket notification programs. To the extent possible, we have included comparative data from previous fiscal years and trend analyses. The report also discusses the device classification program, reclassification, freedom of information, 515(b) regulations, exemptions from premarket notification requirements, and other program related activities. Procedure and policy guidance and other major management initiatives to further implement our policy and program goals and to streamline our procedures are discussed in detail. Specific information about ODE divisional activities is also presented in this report.

II. OVERALL WORKLOAD AND RESOURCES

A. WORKLOAD

ODE experienced an increase in the total incoming submissions during FY 89. We received a record setting 17,635 total submissions for the year which represents an increase of 2,277 documents, or a 15% increase over FY 88. We also received a record number of major submissions: PMAs, PMA supplements, IDEs, IDE supplements, and 510(k)s. The major submissions received rose from 10,018 in FY 88 to 11,195 in FY 89, an increase of 1,177 major submissions or 12%.



Among the major submissions received, there was an unusually high number of 510(k) submissions for examination gloves because of our regulatory activities in the AIDS area. Similarly, we received an onrush of original and supplemental PMAs for IOLs. The filing of these PMA documents by the end of December 1988 enabled the sponsors of IOL studies to continue their adjunct studies.

B. RESOURCES

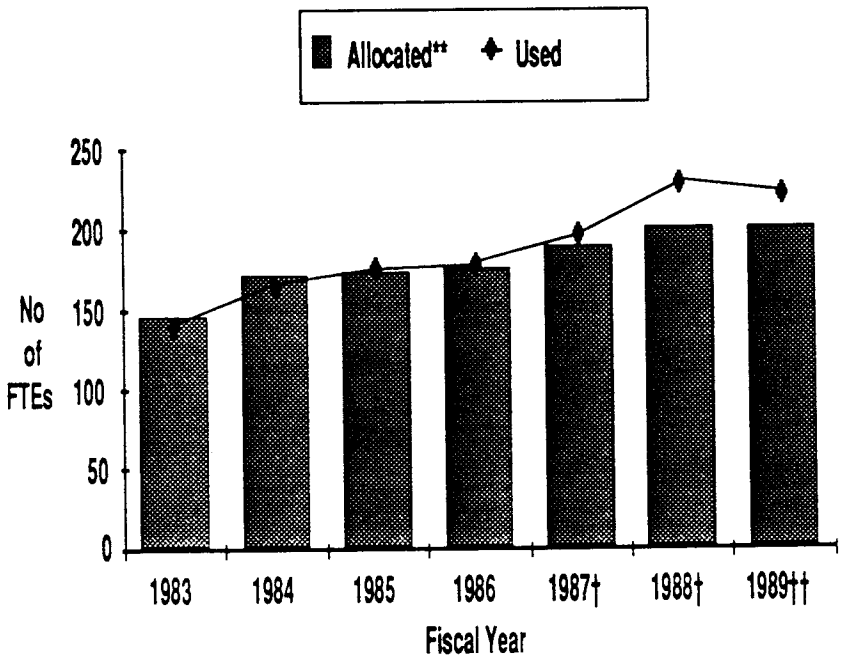
During this past fiscal year we suffered serious losses in ODE staffing. Over the past several years, ODE had an increasing number of "Full Time Equivalents" (FTEs) allocated to its programs. In addition to these increases in ODE's ceiling, during FY 87-89, we were permitted to hire over ceiling based on underutilization elsewhere in FDA. Because of the recent scarcity of resources throughout the Agency, however, we now need to comply with official allocations. As a result, ODE's usage of FTEs dropped from about 230 FTEs in FY 88 to 222 in FY 89.

During FY 89, ODE lost 42 employees (20 scientific reviewers, 1 manager, and 21 support staff). Some of this loss can be attributed to the relocation of the ODE offices. Of the 17 new full-time employees hired in FY 89, 4 were scientific reviewers.

Another major change for ODE this year was the move of its offices from Silver Spring to Rockville. The address for ODE is 1390 Piccard Drive, Rockville, Maryland 20850-4302.

During the period required for the move, June 26, 1989, through July 13, 1989 (18 calendar days), ODE, while continuing to accept

CHART 2 - ODE Full-Time Equivalents (FTEs)*
FY 83 - FY 89



* This chart does not include resources in other Center offices that are applied to product approval.
** The allocated FTEs are official ceilings at the beginning of each fiscal year.
† ODE was allowed to use FTEs in excess of its official ceiling because of FTE under-utilization elsewhere in FDA.
†† ODE was allowed to use FTEs in excess of its official ceiling because of FTE under-utilization elsewhere in FDA. The number of FTEs used in FY 89 includes 14 FTEs which were not available due to the relocation of ODE offices.

mail, did not officially receive premarket notifications, premarket approval applications, or investigational device exemption applications, and did not continue its review of such pending submissions. The statutory review periods on pending submissions were suspended during this 18-day period needed for the relocation of ODE. This action was announced in two letters to submitters and in the *Federal Register* of June 16, 1989, at page 25,705, and September 8, 1989, at page 37,377.

The relocation of ODE offices resulted in the loss of 18 calendar days or 13 work days. This is equivalent to losing about 14 staff members for the year. In addition to the virtual loss of 14 FTEs during that 18 day period, time before and after the move also was lost due to packing, unpacking, lost files and furniture, inoperative and inaccurate telephoning, imbalance in air-conditioning, a sub-par electrical supply, etc. Although there will be long term benefits to be derived from the move, it constituted a serious negative impact on our operations during FY 89.

Despite these setbacks of more than 20 total FTEs and the increases in our workload, we were still able to achieve an exceptional level of performance as documented in this report.

III. MAJOR PROGRAM ACTIVITIES AND PERFORMANCE

This section describes and analyzes activities in the three major program areas which are ODE's primary responsibility, i.e., PMA, IDE, and 510(k). Reference data are contained in the statistical tables and related comparative data are displayed graphically throughout this section.

A. PREMARKET APPROVAL

1. Premarket Approval Applications (PMAs)

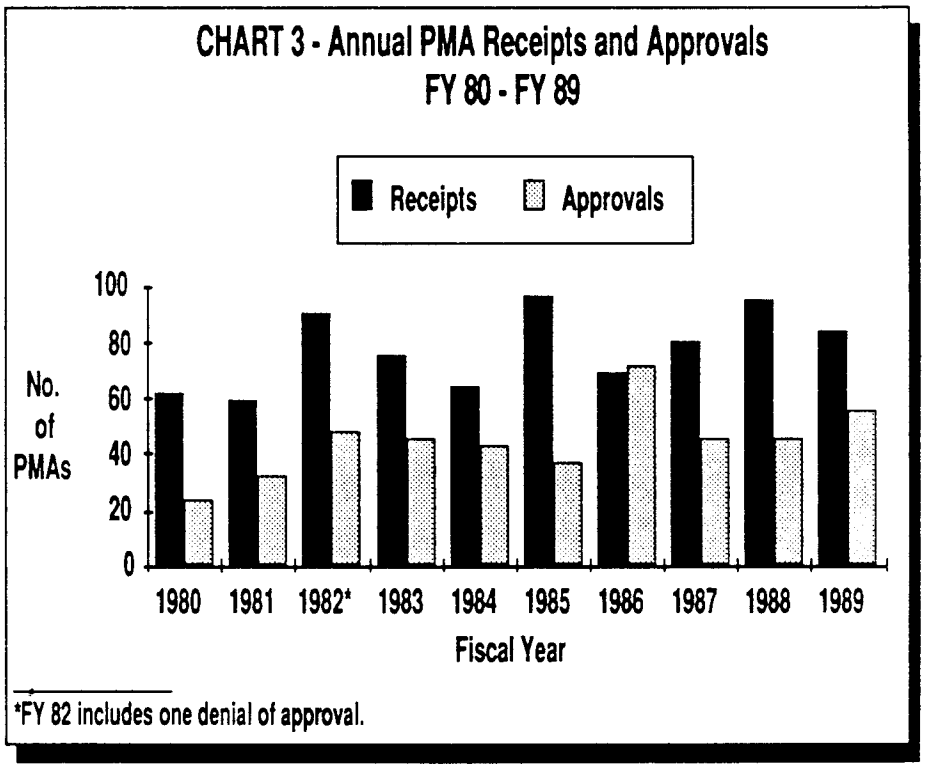
Under the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer or others must submit a PMA for FDA review and approval before marketing a new device. The PMA must provide reasonable assurance that the device is safe and

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 must present the PMA to an expert advisory panel for its recommendations on the application. After obtaining the panel recommendation, the agency makes its 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.

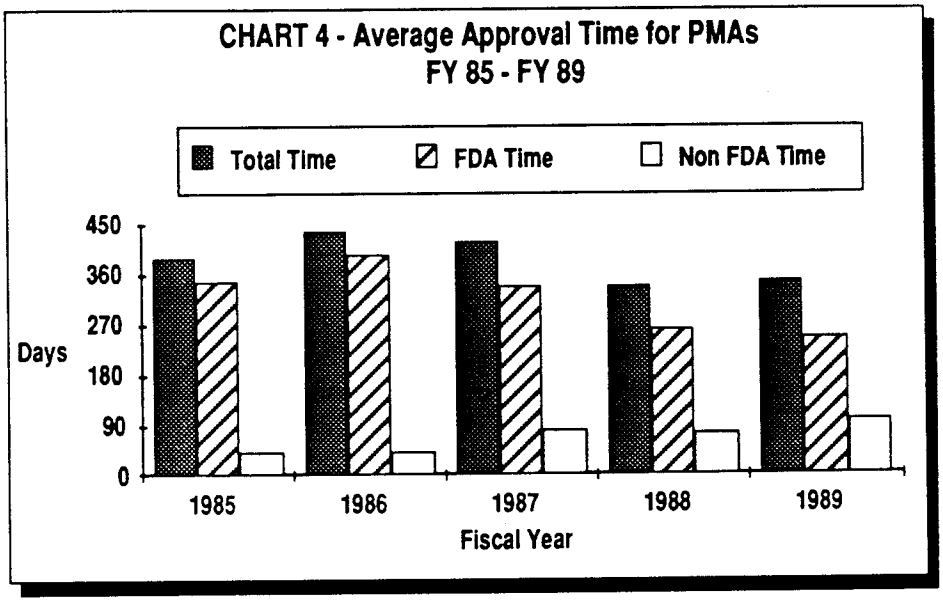
This report includes average FDA review times as calculated in accordance with the provisions of the 1986 PMA regulation, 21 CFR Parts 814. These averages can be found in Tables 2 and 3, Part VII of this report. This regulation establishes a new methodology by which to calculate the statutory time within which FDA must complete its review of original and supplemental PMAs. The method for calculating PMA review time is now the same as that used to calculate review time for new drug applications. In addition, this report continues to carry PMA review times as calculated under the old system so that comparisons can be made between current performance and performances in previous years.

During this fiscal year, 84 original PMAs were submitted. Also in FY 89, we approved the second highest number of PMAs ever approved (56) within one fiscal year. The average FDA review time for PMAs continued to fall, from 262 days in FY 88 to 247 days in FY 89. The average FDA review time, as calculated under the 1986 PMA regulation has leveled off for the first time from 142 days in FY 88 to 145 days in FY 89.

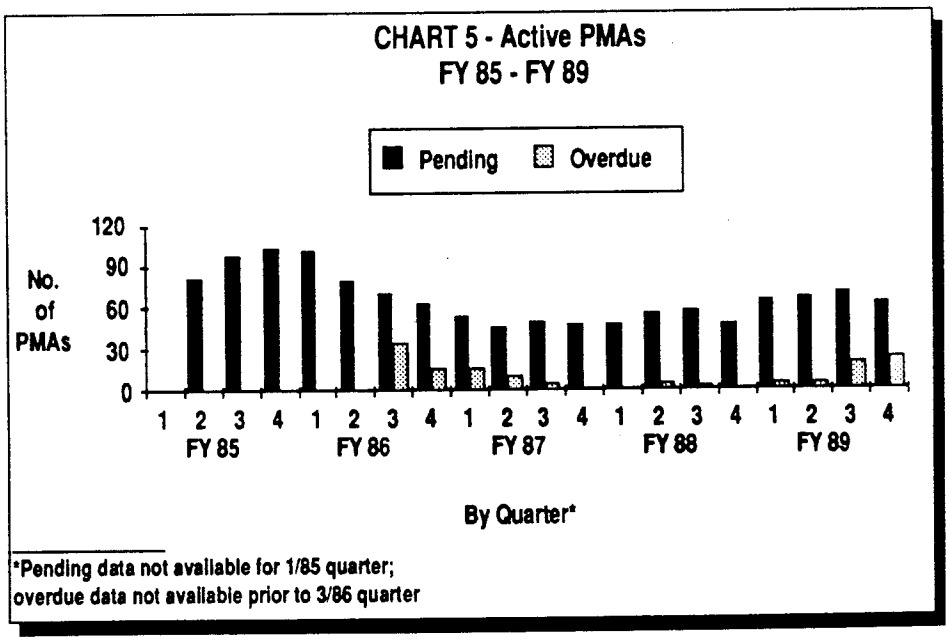
The total PMAs under review at the end of this fiscal year remained constant with last year at 114. Among those under review, the active PMAs went up to 62, from 48 last year, and those on hold went down a bit from last year, from 66 to 52. The number that are active and overdue rose from 1 to 24 since last year.



The total number of PMAs under review at the end of the year and those that were active and overdue were higher than anticipated. This occurred because of the large number of applications we received just before the end of calendar year 1988 for IOLs under studies that were potentially subject to discontinuance by virtue of our phase-out of adjunct studies. This surge within a short period of time was one factor that created a burden on the PMA system. Another factor was the reduction in available resources and the resource loses result-

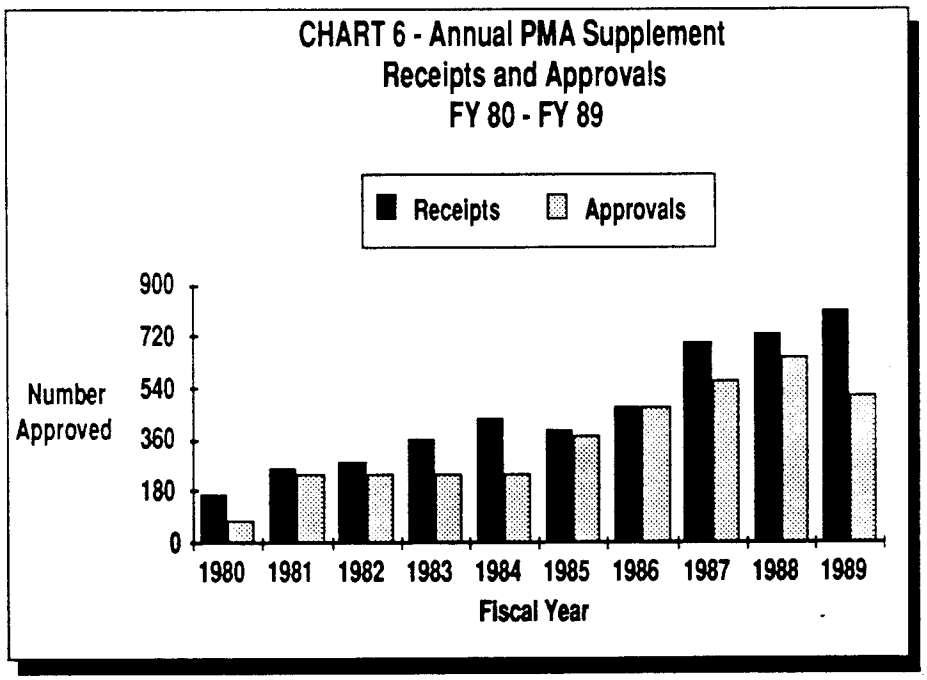


ing from the relocation of the ODE offices. We are working hard to reduce the resulting inventory and backlog and, in response to the extraordinary IOL activity, we set up an IOL Strike Force to work on these applications until they are cleared up.



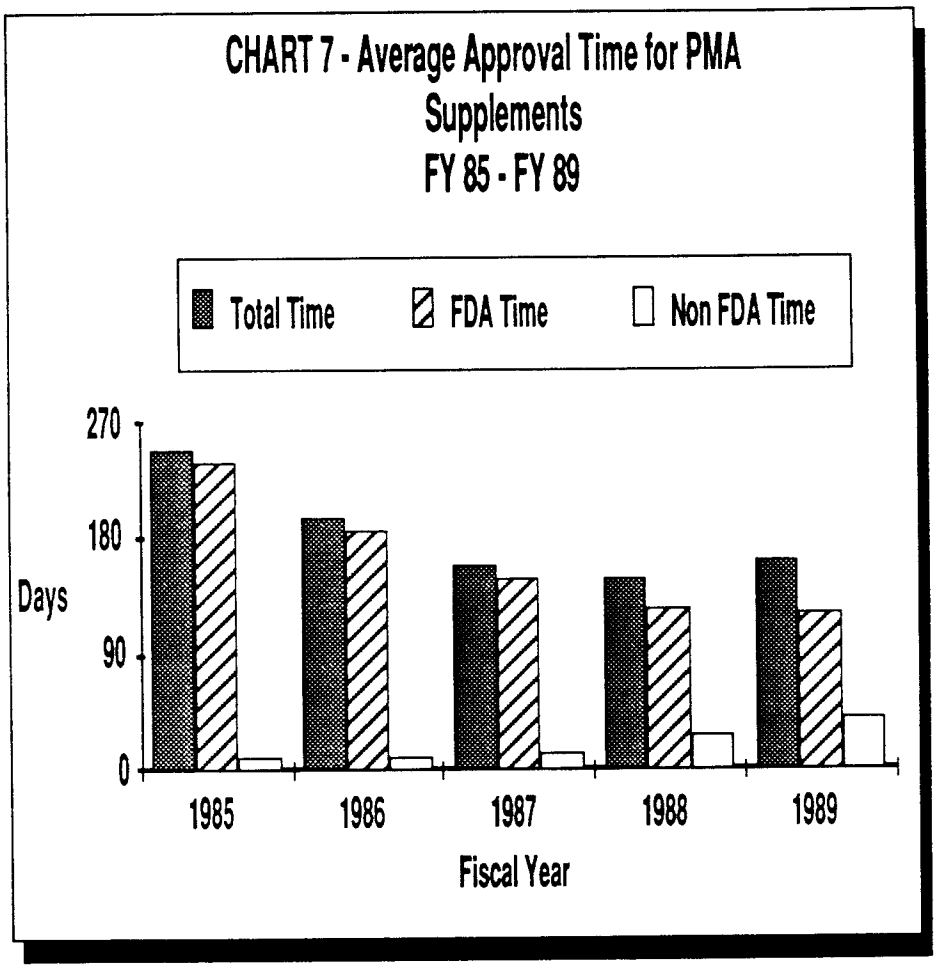
2. PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made 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 procedural regulation, those changes that could affect the safety or effectiveness of the device require FDA approval. FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology.



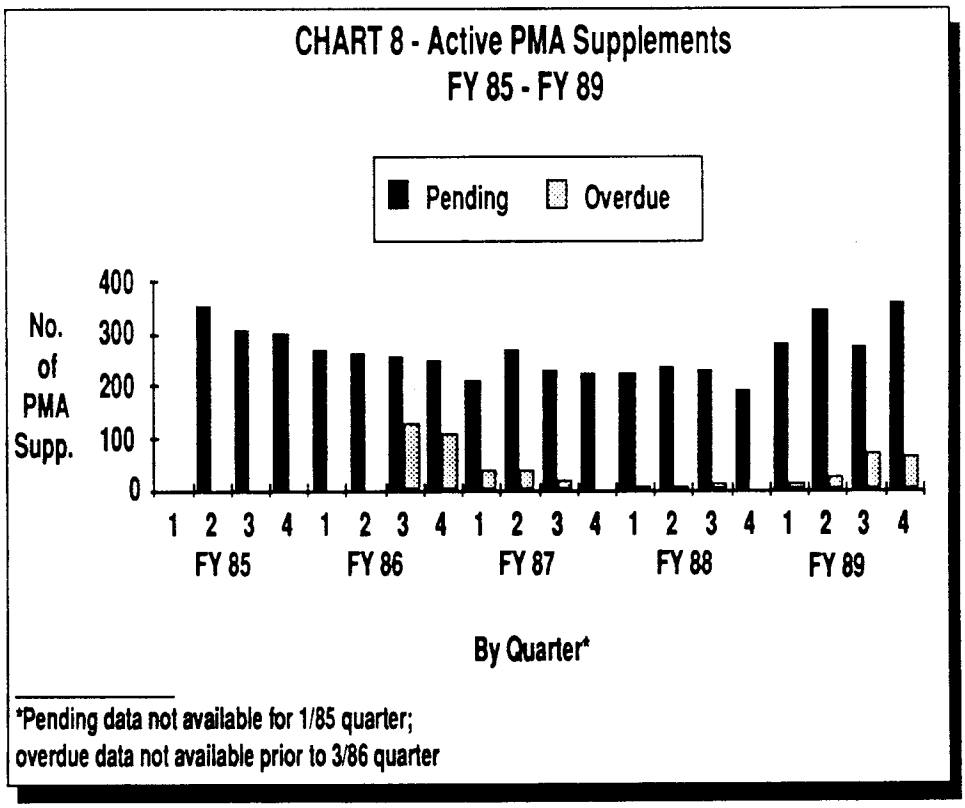
For the fifth consecutive year, we received a record number of PMA supplements, 810 in FY 89 compared to 727 in FY 88, an increase of 11 percent. The number of supplements approved fell to 519 from the record number of 652 supplements

approved last year. This year's approvals, however, included a record number of 13 "panel track" supplements, which are equivalent to original PMAs in reaching an approval decision.



Average FDA review time was reduced from 124 days in FY 88 to 122 days in FY 89, continuing a four year trend. Under the PMA regulation, average FDA review time rose somewhat from 95 to 109 days. The total number of PMA supplements under review at the end of this year rose to 531, from 302 last

year. Likewise, the number of supplements active and overdue also jumped up from two in FY 88 to 68 in FY 89. One of the factors that contributed to these unexpected increases was the surge of submissions received over a very short period of time for IOLs potentially subject to discontinuance under the phase-out of adjunct studies. Another factor was the reduction in available resources and the resource loses resulting from the relocation of the ODE offices. Just as with original PMAs, we are working hard to reduce the resulting inventory and backlog and, in response to the extraordinary IOL activity, we set up an IOL Strike Force to work on these applications until they are cleared up.



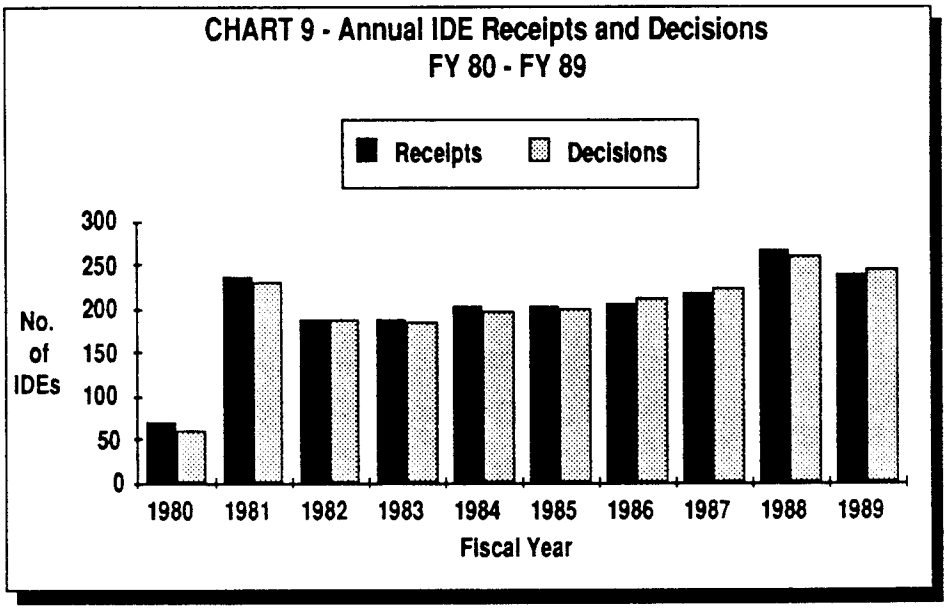
B. INVESTIGATIONAL DEVICES

1. Investigational Device Exemptions (IDEs)

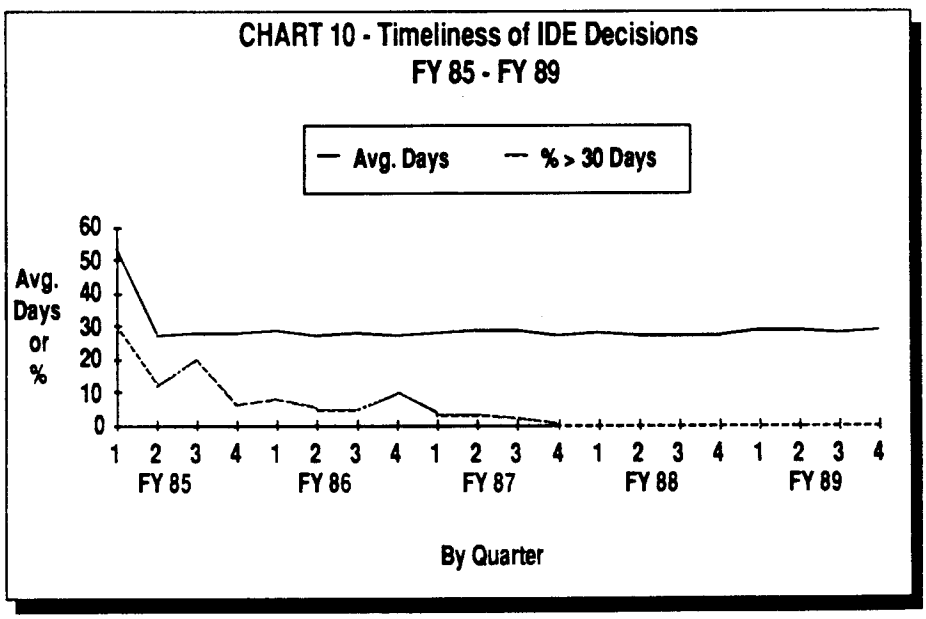
Under the act and regulations, a person may sponsor the clinical investigation of a medical device to establish its safety and effectiveness for a use that has not been approved by FDA. Before conducting clinical trials, however, the sponsor must obtain the approval of an institutional review board (IRB), and, if the investigational device presents a significant risk to subjects, the approval by FDA of an investigational device exemption application (IDE). The IDE must contain information concerning the study's investigational plan, report of prior investigations, IRB actions, investigator agreements, patient consent forms, and other matters related to the study, including preclinical testing of the device. This regulatory scheme is designed to protect the safety and rights of patients while at the same time encouraging the research and development of useful medical devices.

FDA has 30 days from the date of receipt to approve or disapprove an IDE application. If the agency does not act within the 30-day period, the application is deemed to be approved.

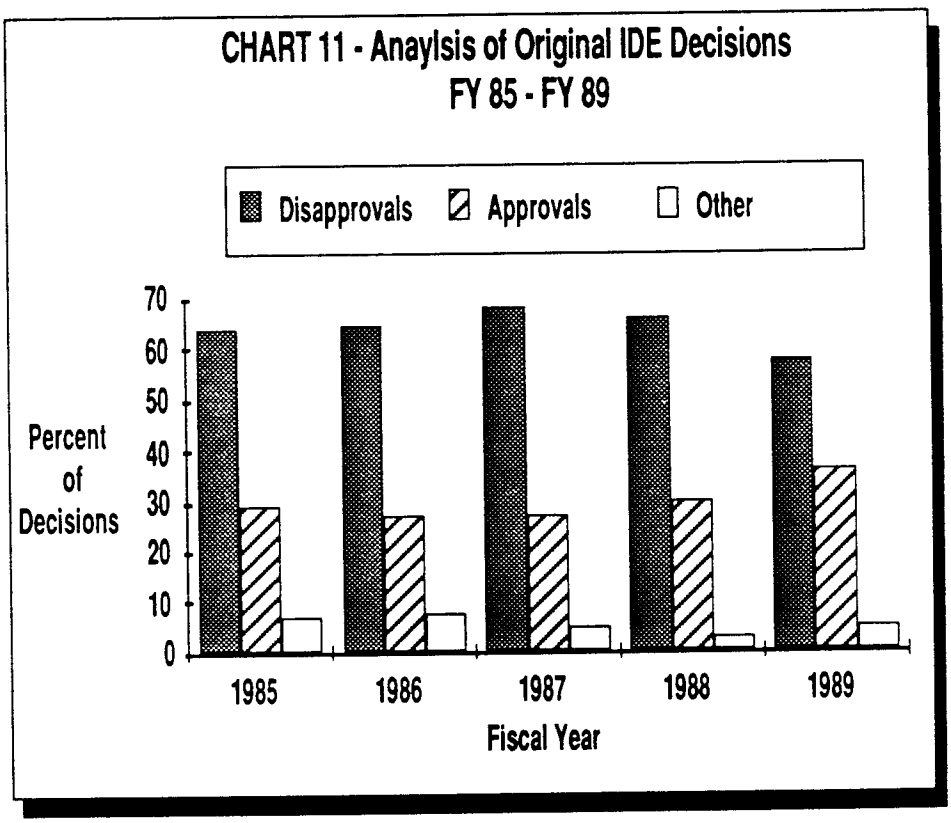
After five consecutive years of increases in the number of original IDEs received, we ended FY 89 with 241 original IDE submissions, down from 268 for the last fiscal year. As expected, the number of decisions were down also, from 260



in FY 88 to 245 this year. Due to the short turn-around time on IDEs, the number of decisions parallels the number of receipts. We had 16 IDEs pending at the close of this fiscal year and none of these was overdue. It took an average of 29 days to review the 245 IDEs and, for the first time in the IDE program, all original IDEs were reviewed within the 30 day statutory review period.



For the first time in these reports we have included, in Table 4, a breakdown of the number of IDE decisions resulting in approvals, disapprovals, and other decisions. Traditionally the number of approvals has been low: 29% in FY 85, and 27% in FY 86 and FY 87. In the last two years, approvals have increased somewhat: 30% and 36% respectively. Although



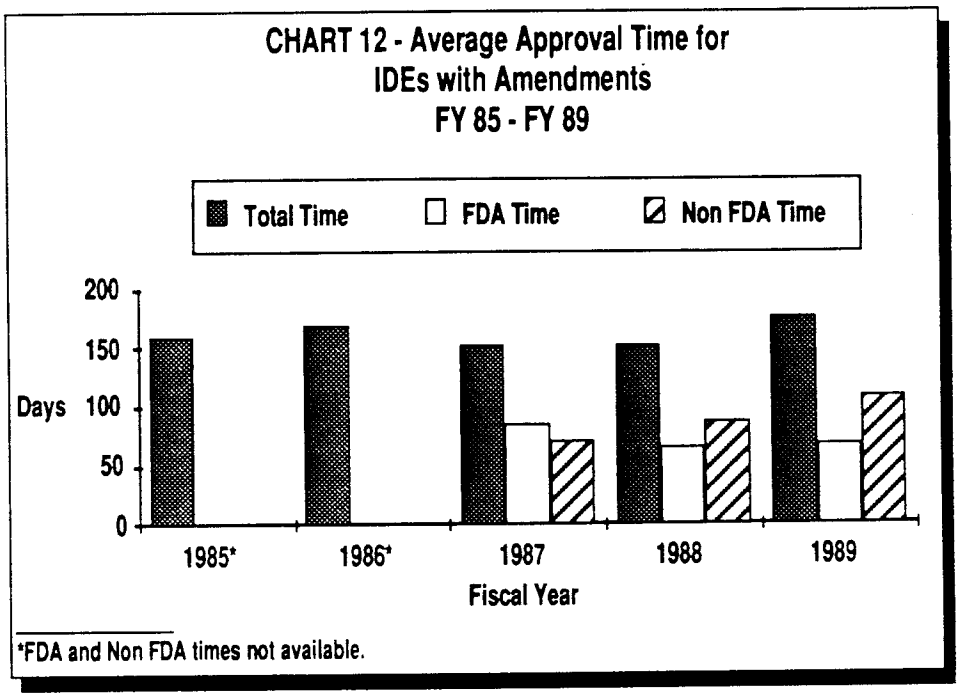
this year's performance represents an increase from previous years in the number of original IDEs that are approved upon their first submission, the majority of IDEs are still not approved upon their first review. In order to achieve the goals of the regulatory scheme designed by Congress, i.e., protection of the safety and welfare of patients while at the same time encouraging the research and development of useful medical devices, FDA and industry must work together to bring about the efficient approval of IDEs.

2. IDE Amendments

Although not provided for in the IDE regulations, we refer to all submissions related to an original IDE that has been previously disapproved as an IDE amendment. Submissions related to an IDE after it is approved are supplemental applications under the regulations. Identification of IDE amendments enables FDA to track each original IDE from the time it is initially submitted, and disapproved, to the time it is approved or abandoned. An amendment may be initiated by the sponsor or it may be submitted in response to an inquiry by FDA. The content of an amendment may relate to any matter that is the subject of an original IDE.

During this fiscal year we received 271 amendments, down from 316 received in the last fiscal year. We made 280 decisions on amendments: 127 approvals (45%); 78 disapprovals (28%); and 75 other administrative actions (27%). Ninety-nine percent of these decisions were made within 30 days. At the end of FY 89 there were 11 amendments awaiting decision and none of these were overdue.

Each amendment is associated with an original IDE. Thus, approval of an amendment constitutes the approval of an original IDE. Most IDEs are ultimately approved this way. For example, in FY 89, 58% of all original IDEs were disapproved while only 36%, the highest in the last five years, were approved. During FY 89, the 127 amendments approved were related to 109 original IDEs. The additional 18 amendments were related to some of these same original IDEs and were approved simultaneously.



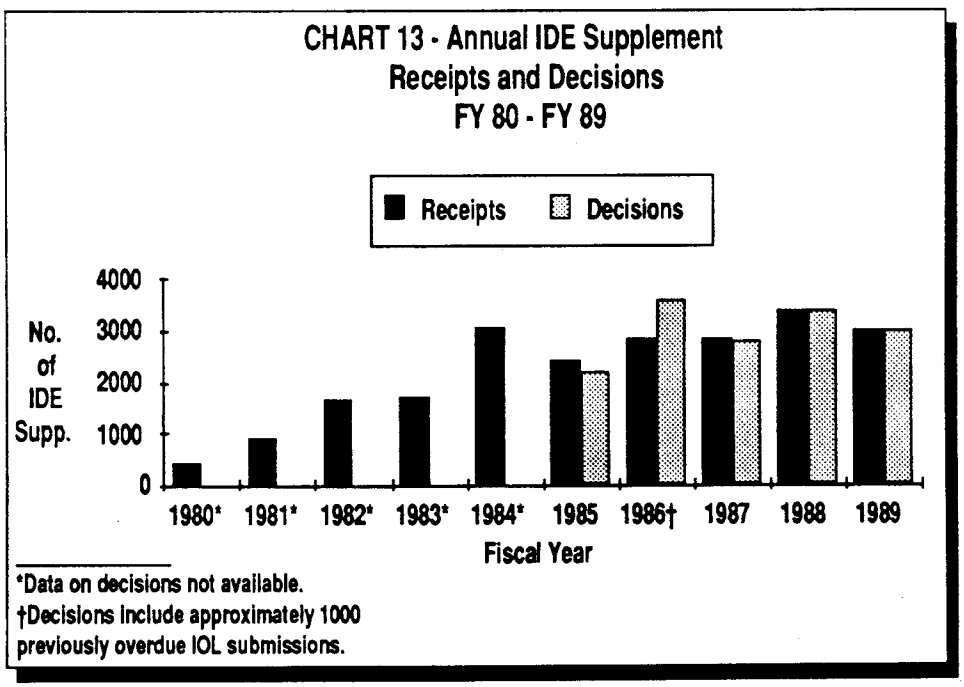
Some of the IDEs approved through amendments this year were originally submitted in prior fiscal years. The oldest goes back to December, 1986. The most amendments associated with an IDE approved this year was five. The average number of amendments per originally disapproved IDE approved in FY 89 was 2.7. We would like to lower this average and will work with industry to accomplish this goal.

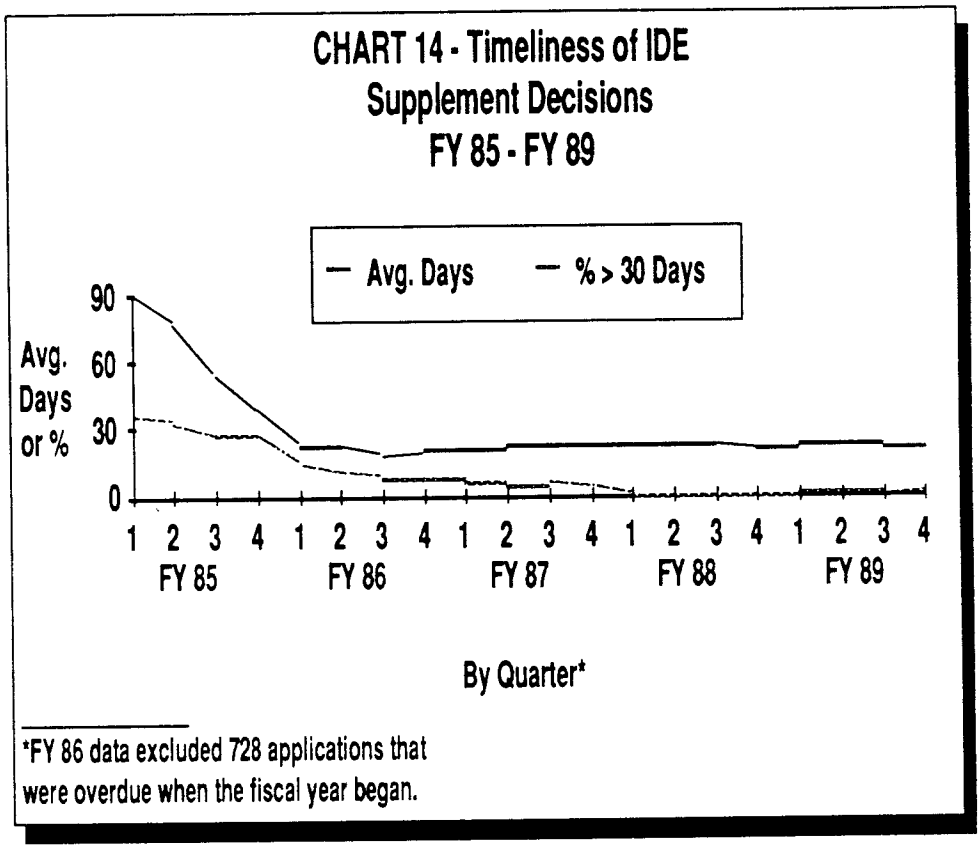
The average total time to approve the amended IDEs this year was 176 days and the longest time for approval was 744 days total time (combined FDA and nonFDA time). The average number of days FDA has taken per amended IDE approved was 68 days, while the nonFDA time averaged 108 days. For the last three years, the only period for which such data is available, the FDA time has fluctuated between 83 and 65 days. The nonFDA time has been increasing for the last three years going from 69 days in FY 87 to 87 days in FY 88 and 108 days in FY 89.

3. IDE Supplements

The IDE regulation requires that the sponsor of an investigation of a significant risk device submit a supplemental application if there is a change in the investigational plan, whenever such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. The sponsor also must submit a supplement if a new investigational site is being added, in which case certification of the reviewing IRB's approval must be submitted. The supplements must update information previously submitted in the IDE application, including any modifications to the investigation.

This regulation also requires the submission of various reports which are logged in as supplements to the IDE applications. These include reports on unanticipated adverse device effects, recall and device disposition, and failure to obtain informed





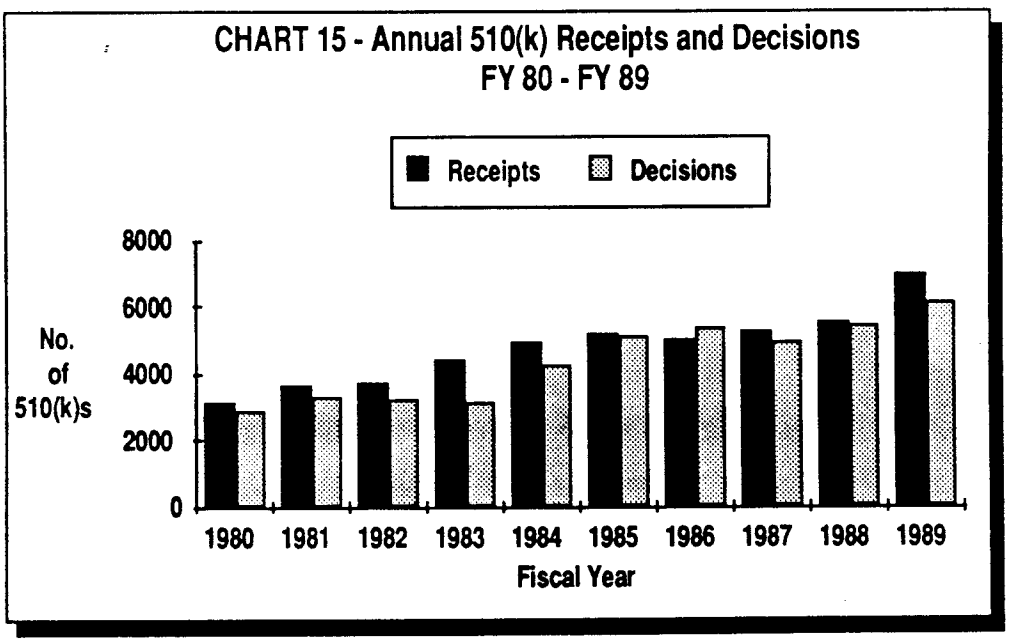
consent, as well as annual progress reports, final reports, investigator lists, and other reports requested by FDA.

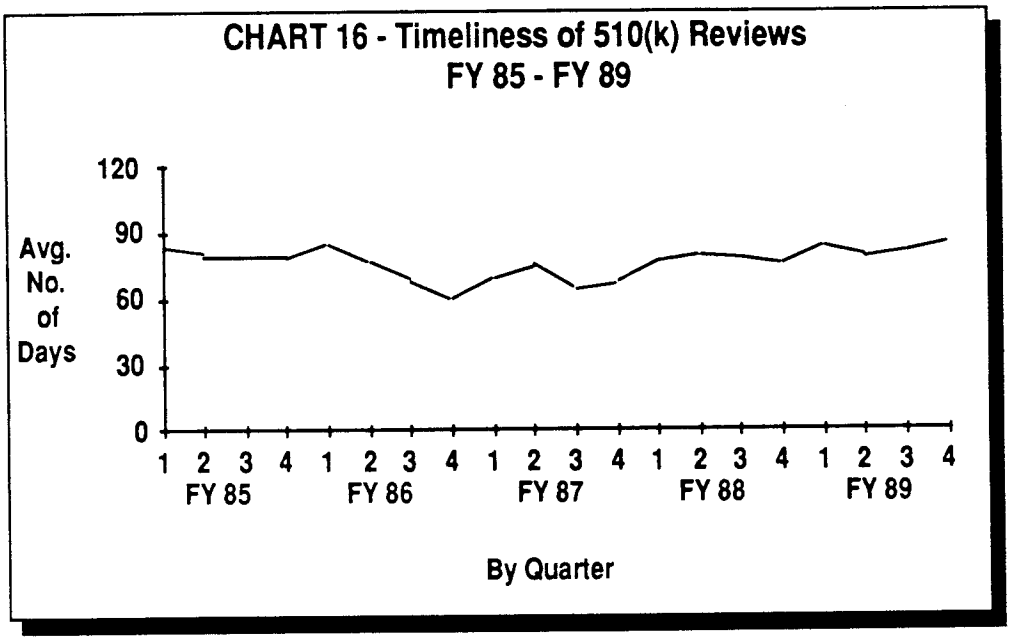
We received the second highest number of IDE supplements last year, 3,038, which represents a decrease of 353 submissions from the 3,391 submissions we received in FY 88. Accordingly, the number reviewed also dropped, from 3405 in FY 88 to 3,023 in FY 89. The number under review at the end of FY 89 rose slightly, from 157 last year to 170 this year. There were no overdue supplements at the end of the fiscal year and the number of IDE supplements that were reviewed within the statutory time frame of 30 days remained constant at 99 percent. Average review time for completing the review of IDE supplements also remained constant at 22 days.

C. PREMARKET NOTIFICATIONS (510(k)s)

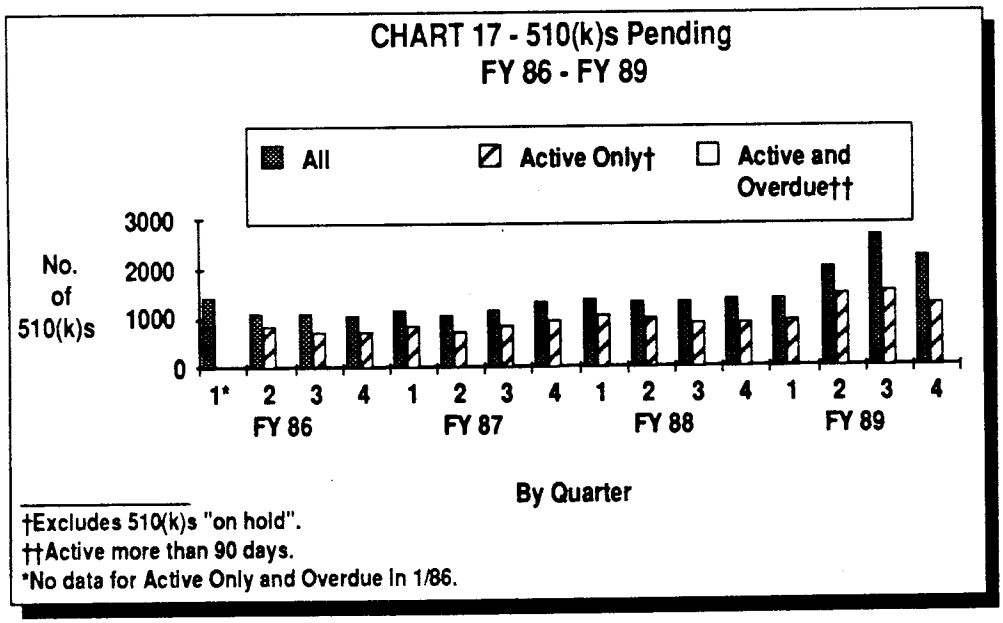
At least 90 days before placing a medical device into commercial distribution, a manufacturer or distributor must file with FDA a premarket notification, commonly known as a 510(k). In addition to a description of the device, the 510(k) may also include a claim that the device is substantially equivalent to a pre-Amendments device. "Substantially equivalent" devices may be marketed subject to the same regulatory controls as their pre-Amendments predecessors. If the device is not substantially equivalent, the manufacturer may petition for reclassification, submit a PMA to market the device, or submit an IDE to conduct a clinical investigation.

The number of 510(k)s received rose dramatically to 7,022 for FY 89 from 5,536 in FY 88, an increase of 1,486 submissions or 27 percent. This is the third consecutive year we have experienced significant increases in 510(k) submissions. Final decisions on



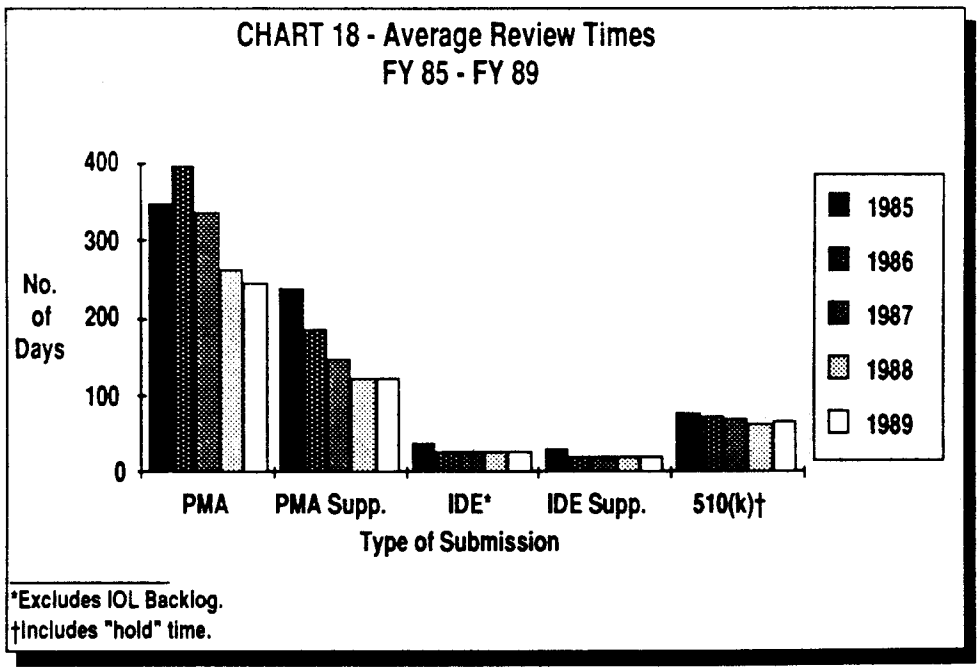


510(k)s also rose dramatically during FY 89 to 6,136, up from 5,513 the previous year for an increase of 623 decisions or 11 percent. Average review time based on both total time and FDA time rose somewhat over last fiscal year, from 78 to 82 days and 64 to 66 days, respectively. Both of these average review times include all increments of both FDA and nonFDA times for a 510(k). This



is true regardless of how often the 510(k) review clock is restarted because a 510(k) is amended, so long as the 510(k) number does not change, which happens only rarely. Nevertheless, 99% of all 510(k) decisions were made within the 90 day statutory review period, after allowing for the 18 days during which the Document Control Center was officially closed. Furthermore, there were no 510(k)s on hand that were active and overdue at the end of the fiscal year.

The number of 510(k)s under review at the end of the year also went up, significantly, from 1,358 in FY 88 to 2,259. This was due in large part to three major factors: the surge in submissions for examination gloves resulting from FDA's activity on AIDS related regulatory matters, the general increase in the number of submissions, and the office move. To cope with the tremendous number of examination glove submissions, a special group was formed to deal with them until the inventory of these documents is cleared out.



D. SIGNIFICANT MEDICAL DEVICE BREAKTHROUGHS

We cleared for marketing seven new devices during FY 89 that represent significant advances in medical device technology.

- The Interceed™ Absorbable Adhesion Barrier, approved for marketing on September 15, 1989, is an adjuvant in gynocologic pelvic surgery for reducing the incidence of postoperative pelvic adhesions after hemostasis is achieved consistent with microsurgical principles.

- The Cook Bird's Nest Vena Cava Filter was approved on April 26, 1989. It is used for filtration of inferior vena cava blood to prevent pulmonary thromboembolism (PTE) in patients for whom anticoagulant therapy is contraindicated or in whom there may be complications with anticoagulant therapy, in patients in whom PTE is recurrent despite anticoagulant therapy, and, prophylactically, for high risk patients with deep vein thrombosis or prior to surgery.

- The ViraPap™ in vitro diagnostic device was approved on December 23, 1988. This is the first commercially available device to utilize a cocktail of nucleic acid probes for the detection of any of seven specific human papillomavirus types that can infect the human cervix. This device is used to aid in the diagnosis of sexually transmitted human papillomavirus infections which are associated with the majority of cervical lesions. The device also may serve as an adjunct to the Pap smear in the identification of women who may be at increased risk of developing cervical intraepithelial neoplasia. Prior to

the availability of these DNA probes, none of the seven human papillomavirus types could be identified by routine laboratory tests.

- The MAK-6 in vitro diagnostic device, which was cleared for marketing in October 1988, utilizes two monoclonal antibodies to detect cytokeratins, which are proteins in human cells. The test's ability to detect the presence of certain cytokeratins improves the clinicians ability to classify tumor cells as being a certain epithelial type. The device, thus, is used to assist in the differentiation of malignant tissues of epithelial origin from other non-epithelial malignant tissue.

- The PACE Urine Screen, an in vitro diagnostic device used to screen for bacteria in urine, was cleared for marketing in September 1989. This represents the first nucleic acid probe for aid in the detection of urinary tract infections. This nucleic acid probe enables the clinical laboratory to speed up the identification of urinary tract infections which, in turn, allows the physician to more rapidly diagnose the patient's condition.

- The Prostatic Urethroplasty Balloon Dilation Catheter cleared for marketing in July 1989. This is the first catheter intended to treat benign prostatic hypertrophy.

- The Belzer UW-CSS Solution was cleared for marketing on April 20, 1989. This product is a sterile, nonpyrogenic solution used for the hypothermic flushing and storage (preservation) of human organs in preparation for transplantation. This product is intended to extend the preservation time over earlier solutions for the storage of the pancreas and liver.

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

During FY 89, ODE and its operating units issued the following instructional materials for use by manufacturers and ODE reviewers. These guides identify changes in procedures and policies and clarify requirements applicable to our approval program. They are intended to promote uniformity and efficiency in program implementation. Most of these guidance documents are available through the Division of Small Manufacturers Assistance (HFZ-220), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (800) 638-2041.

- Premarket Notification - Consistency of Reviews. On February 28, 1989, we issued a "Blue Book" memorandum to outline methods of identifying important issues that require uniform treatment across the divisions of the Office of Device Evaluation, for developing guidance on these issues, and for ensuring proper implementation in the review of premarket notifications (510(k)s) for the purpose of achieving a high level of consistency in the review process. It covers the topics of documentation, crosscutting issue identification, implementation of new guidance procedures, and monitoring implementation.

- Review of IDE's for Feasibility Studies. On May 17, 1989 we issued a "Blue Book" memorandum which details the purpose and procedure for the review of IDE applications for feasibility studies involving limited numbers of human subjects. This guidance will facilitate feasibility studies while at the same time protect the subject's safety and welfare.

- 510(k) Sign-Off Procedures (Revised). On June 8, 1989, we issued a "Blue Book" memorandum as a revision to the earlier memorandum of February 17, 1986, to clarify which types of 510(k) decisions may be signed out by the Division Director, the Division Director's designee, and the ODE Associate Director. It also establishes procedures for the foregoing. These changes should further streamline the 510(k) procedures.

- Telephone Notification for 510(k)s Under Review for 75 Days or Greater. On June 8, 1989, ODE issued a new "Blue Book" memorandum to require ODE staff members to call the submitter of any 510(k) for which a decision letter had not been issued by the 75th day after receipt. This applies to all 510(k)s placed on hold, not substantially equivalent decisions, not a device decisions, and substantial equivalency decisions with specific conditions. This telephone notification must be made before the 90 day review period expires. This guidance should ensure that devices are not marketed without clearance from FDA.

- Training for ODE Employees. On July 14, 1989, a comprehensive "Blue Book" memorandum was issued to clarify for

all ODE employees the government sponsored training available to them and to explain the purpose and principles of this training.

- Toxicology Risk Assessment Committee. On August 9, 1989, ODE issued a "Blue Book" memorandum to establish a Center-wide Toxicology Risk Assessment Committee and describe the initial operating procedures for the Committee. The Committee will review the applications that are potentially problematic, that present sensitive, highly visible issues, or that may result in precedent-setting toxicology decisions. It will also review toxicology-related product approval guidance documents.

- Contact Lens Testing Guidance. During April, 1989, the Division of Ophthalmic Devices (DOD) issued a revised guidance for evaluating the safety and effectiveness of Class III contact lense. This document revises previous guidance and provides acceptable state-of-the-art methodologies and standardized testing procedures for lenses.

- Salt Tablet Labeling. In December, 1988, as a result of a Center for Disease Control (CDC) report on the association of homemade saline solutions and acanthamoeba keratitis, DOD requested that manufacturers of salt tablets revise the labeling and indications for their product and strengthen the directions for use.

- Salt Tablet Safety Alert. On January 24, 1989, CDRH issued a Safety Alert on homemade saline solutions for contact

lenses. This alert, directed to eye care practitioners and salt tablet users, warned of the hazards of improperly using home-made saline solutions in caring for contact lenses. The alert was based on a CDC study that found an association between acanthamoeba keratitis and the use of salt tablets.

- Definition of Disposable Contact Lenses. At the October 21, 1989 meeting of the Ophthalmic Device Advisory Panel, DOD issued guidance defining "disposable contact lenses" as lenses for which there is no indication for reuse. The policy also defined what claims could be made and what labeling was required for these lenses.

- 7-day Extended Wear Contact Lenses. On May 30, 1989, ODE issued a letter to manufacturers of contact lenses requesting changes in the labeling to reduce the wearing time indication to a maximum of seven days between removals and to provide certain new warnings. At the same time, letters were sent to all eye care practitioners indicating that the device labeling for the time period between lens removal for cleaning was being reduced to a maximum of 7 days from the previous 30 days. This change was a result of a study that found that the risk of ulcerative keratitis increased with increasing duration between removals for cleaning.

- Review of UV Absorbing Posterior Intraocular Lenses. On July 31, 1989, ODE issued a guidance changing the approval procedure for posterior chamber IOLs with approved PMAs that are subsequently modified by the addition of a UV absorber. We indicated that PMA submissions for these lenses would no longer require individual panel review but rather

could be approved following an administrative track. Panel review and the preparation of a summary of safety and effectiveness would only be required if the submission requested new claims or if questions of safety and effectiveness arose.

- Waiver of Prior Notification and Approval for Minor Tier A Changes in IOLs. On August 14, 1989, ODE issued a letter to manufacturers indicating that certain physical changes to IOLs with approved PMAs would no longer require the submission of a supplemental PMA application. The change could instead be reported to the agency in annual reports. This change is a result of DOD's continuing review of its requirements and procedures for approving IOLs.

- Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter Guidance. In February 1989, the Division of Cardiovascular Devices (DCD) revised this document to incorporate technological change in the field of PTCA relative to both new catheter design and new indications, e.g., perfusion catheters. Included is clarification of the presentation of clinical data in support of the investigational catheter claims, such as claims of investigational success when catheters of two or more manufacturers were utilized in the procedure. The document is sent to manufacturers on request and prior to study design for an IDE/PMA.

- Laser Catheter Guidance. In November 1988, DCD revised this document to reflect the technological changes that have occurred and to add the new indications for use that have emerged with clinical trials. The document is sent to manufacturers on request.

- Valvuloplasty Guidance. In January 1989, this document was revised to make it consistent with the newly revised PTCA document, discussed above, and to update the indications for use.

- Vascular Graft Guidance. This is a new guidance written with the help of the research community and product developers and has been made available to manufacturers upon request since October 1988. The paper outlines both the types of testing necessary and the suggested clinical study design to be submitted to FDA for review.

- Intraaortic Balloon Pump Guidance. DCD developed this working draft in January 1989 to establish the engineering information needed to demonstrate substantial equivalence to currently marketed devices. This document is sent to manufacturers upon request.

- Pacemaker Test Guidance. In August 1989, a revision was made to this document to clarify bench testing requirements, to change the dimensions of the clinical study, and to explain changes in the reporting requirements. The document is being made available to pacemaker manufacturers and their associations.

- Programmer Module Guidance. In April 1989, a new guidance document was issued that permits manufacturers to list an unapproved pulse generator on the menu of a programmer under the conditions that the generator has been tested and will soon be submitted to FDA for approval.

- Revised Conditions of Approval for Pacemakers. This document was issued in September 1989 in response to industry

requests to remove the duplication of failure reporting for pacemakers. The document now asks for information on survivability of pacemaker failures in a more readable summary form, a cumulative survival table, and descriptions of all failures. The Health Industry Manufacturer's Association will mail the document to all holders of pacemaker approvals.

- Fetal Doppler Ultrasound. The Division of OB-GYN, ENT and Dental Devices (DOED) spearheaded the development of premarket testing guidelines for Doppler ultrasound instrumentation intended for fetal applications. For almost ten years, FDA has considered this promising use of Doppler instrumentation to be investigational. These guidelines were reviewed and endorsed by the Panel at its January 19, 1989, meeting. A Notice of Availability of these guidelines was published in the *Federal Register* on September 8, 1989. Several such systems have now cleared through the 510(k) review process.

- PMA Guidance for Endosseous Implants for Prosthetic Attachment. In May 1989, the final guidance was distributed to the medical community and to manufacturers of endosseous implant. This guidance describes the information manufacturers must provide in a PMA submission to allow adequate review by FDA and the ENT Devices Panel.

- Examination Glove 510(k)s. In January, 1989, we issued a suggested format for examination glove 510(k)s. The guidance was instrumental in streamlining the review of the more than 1500 510(k)s received and greatly aided manufacturers in preparing their submissions. The format also enabled OST to prepare an automated software review program for examination gloves.

B. CLASSIFICATION OF MEDICAL DEVICES

When the Medical Device Amendments of 1976 were enacted, Congress mandated that FDA classify each device then in commercial distribution into one of the three designated regulatory classes, i.e., class I - General Controls, class II - Performance Standards, and class III - Premarket Approval.

In FY 89, FDA proposed the classification of 70 electromedical devices into class I. These devices were originally proposed for classification into class II but final classification was postponed. The reproposal was published in the *Federal Register* of November 15, 1988.

C. RECLASSIFICATION OF CLASSIFIED DEVICES

The following actions occurred during FY 89 concerning the reclassification of medical devices.

- Issued the order on reclassifying the ceramic hip prosthesis from class III to class II on December 5, 1988.

- Published the final rule in the Federal Register on June 28, 1989 announcing the reclassification of $PcCO_2$ monitors from class III to class II.

- Issued the order on reclassifying the absorbable poly(glycolide/L-lactide) surgical suture from class III to class II on September 14, 1989, to become effective on October 4, 1989.

- Issued a letter on August 23, 1989 denying the reconsideration petition concerning the September 19, 1988 order reclassifying the absorbable surgical gut suture from class III to class II.

- Published the proposed rule in the *Federal Register* on April 4, 1989 to reclassify the automated differential cell counter from class III to class II.

- Obtained a Panel recommendation on October 20, 1988 to reclassify the nonabsorbable poly(ethylene terephthalate), polypropylene, and silk surgical sutures from class III to class II.

- Obtained a Panel recommendation on March 10, 1989 to reclassify the suction lipectomy system from class III to class II.

- Obtained a Panel recommendation on September 22, 1989 to reclassify the porous-coated hip prosthesis from class III to class II.

- Filed the petition for reclassifying the Argon laser for rhinology and laryngology from class III to class II.

D. PMAs FOR PRE-AMENDMENTS DEVICES (515(b) REGULATIONS)

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

Nearly 150 generic types of devices have been proposed for, or have been finally classified in, class III. Recognizing that FDA could not issue 515(b) regulations simultaneously for all pre-Amendments class III devices, Congress authorized FDA to establish priorities which may be used in applying premarket approval requirements to these devices. On January 6, 1989, FDA published an advanced notice of proposed rulemaking in the *Federal Register* to announce its intent to issue 515(b) regulations for an additional 31 Class III pre-Amendments devices having a high priority for the application of premarket approval requirements.

In prior years, 515(b) rules have been promulgated for various high priority devices. During this fiscal year, we published, in the *Federal Register* of December 1, 1988, a final rule requiring the filing of a PMA for the implanted intracerebral/subcortical stimulator for pain relief. This rule became effective on March 1 1989.

E. EXEMPTIONS FROM PREMARKET NOTIFICATION

Under Section 513 of the Federal Food, Drug, and Cosmetic Act, (the act), FDA may exempt, by regulation, a generic type of Class I device from the requirements of, among other things, premarket notification in section 510(k) of the act and 21 CFR Part 807, Subpart E. Such an exemption allows manufacturers to introduce devices into commercial distribution without first submitting to FDA a premarket notification (510(k)), which reduces the number of 510(k)s on relatively innocuous devices while freeing agency resources for the review of more complex devices. These exemptions usually contain certain limitations depending upon the device's intended use or the fundamental scientific technology used in the device.

During FY 89, FDA published in the *Federal Register* during FY 89, the following final 510(k) exemption notices for the types of class I devices listed.

Final exemption rule published on April 5, 1989:

- General and Plastic Surgery - 8 devices.
- Radiology - 4 devices.
- Dental - 22 devices.

Final exemption rule published on June 12, 1989:

- Hematology and Pathology - 24 devices.
- Immunology and Microbiology - 37 devices.
- Anesthesiology - 13 devices.
- Cardiovascular - 3 devices.
- Gastroenterology-Urology - 9 devices.
- General Hospital and Personal Use - 6 devices.
- Neurology - 7 devices.
- Obstetric and Gynecology - 3 devices.
- Physical Medicine - 2 devices.

F. ADVISORY PANEL ACTIVITIES

Under specific provisions of the Act or regulations, or upon its discretion, FDA may convene an advisory committee (panel) meeting. The purpose of the panel meeting is to conduct a public hearing under Title 21, Part 14, of the Code of Federal Regulations to review and make recommendations on certain matters under consideration by the Agency. Such matters include the classification of medical devices, review of PMAs and PDPs, proposed reclassifications of classified medical devices, and other pending actions.

During FY 89, the following medical device panels, set up according to medical specialty, held public hearings to review and make recommendations on matters under consideration by ODE.

During the past year, ODE also undertook some major initiatives to provide greater support to panel activities. An Advisory Panel Coordinator was appointed, who will develop policies and procedures that will promote consistency and efficiencies among ODE panels. One immediate goal is to develop materials that will be used to orient and educate advisory panel members on the scope of the panels' functions and their roles in the regulatory review process. A second major goal is to create a more flexible system for the utilization of the expertise of the panel members, which may involve rechartering of the panels.

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 processed more than 1,500 FOI requests during FY 89.

H. PUBLICATIONS

During FY 89 the Information Clearance Committee processed three articles authored by ODE staff for publication in professional and scientific journals and 22 presentations to be delivered by ODE staff at professional and scientific and trade association meetings.

CHART 19 - ODE Advisory Panel Meetings
FY 89

Panel (Executive Secretary)	Number of Meetings	Meeting Days
Dental (Gregory Singleton)	2	3
Obstetrics-Gynecology (Raju G. Kammula)	4	6
Ear, Nose, and Throat (David A. Segerson)	1	1
General and Plastic Surgery (Paul F. Tilton)	5	5
Orthopedic and Rehabilitation (Marie Schroeder)	3	3
Gastroenterology/Urology (Ruth W. Hubbard)	1	2
General Hospital and Personal Use (Timothy A. Ulatowski)	—	—
Ophthalmic (Daniel W. C. Brown)	4	7
Radiology (Adrianne Galdi)	1	2
Neurology (Robert F. Munzner)	1	1
Anesthesia and Respiratory Therapy (Diane E. Minear)	1	1
Circulatory Systems (Keith Lusted)	4	4
Microbiology (Joseph L. Hackett)	2	2
Hematology and Pathology (Joseph L. Hackett)	1	2
Clinical Chemistry and Toxicology (Kaiser J. Aziz)	2	2
Immunology (Srikrishna Vadlamudi)	—	—
Totals	32	41

V. ODE DIVISION ACTIVITIES

A. GENERAL RESPONSIBILITIES

Divisions within ODE are the main units that review applications and evaluate the safety and effectiveness of medical devices, the appropriateness of clinical investigations, and whether a device is substantially equivalent. The bulk of our scientific and professional expertise resides in the divisions. The divisions are comprised of branches and, in one case, the branches are broken down into sections. The organizational chart in Appendix A identifies ODE's divisional structure and each division's leadership.

ODE has seven divisions, each responsible for devices that fall within certain medical specialty areas. There is some overlap in the review of certain devices for which the indications of use fall within different medical specialty areas or for the review of which a particular scientific or professional expertise is required, e.g., lasers, ultrasound, and a few others. Each division and the highlights of its activities for the past fiscal year are discussed below.

B. DIVISION REPORTS

The following summaries were prepared by each ODE division to highlight the major events within the division during FY 89.

1. Division of Anesthesiology, Neurology and Radiology Devices (DANRD)

The DANRD finished FY 89 with an exemplary record. All applications for the year were reviewed on time and showed sound scientific judgement and actions. During the past fiscal

year, DANRD has worked towards the resolution of a number of public health and policy issues that will facilitate and provide more efficient means of regulating devices for which DANRD has responsibility. The issues dealt with included technical specifications and standardized testing techniques for magnetic resonance diagnostic devices, data requirements for apnea monitor 510(k) submissions, and data that constitutes "valid scientific evidence" for pain therapy devices.

Working with the Center's Office of Health Affairs, the CDRH Human Tissue Products Working Group, and DSRD, DANRD has collaborated in the development of options for the regulatory control of processed human dura mater in a manner that will be accepted by the industry and will provide the necessary safe guards to protect the public health. Both the American Association of Tissue Banks and the Southeast Organ Procurement Foundation provided considerable data to the Neurological Devices Panel that may be used if classification becomes the regulatory method of choice.

2. Division of Cardiovascular Devices (DCD).

The DCD ended FY 89 with an excellent record of accomplishments in the areas of productivity and scientific judgement. Several "first of a kind" devices such as a collagen coated vascular graft, a patent ductus arteriosus occluder and a vena cava filter were approved through the PMA process.

The DCD staff of twenty eight handled a record number of marketing applications and other complex and controversial scientific and regulatory issues. The staff morale is good and

DCD was fortunate in not suffering any attrition in its scientific staff.

The DCD continues to collaborate with other CDRH offices on projects such as an MDR pilot project to make the data base more informative and user friendly, research projects on heart valves, and vascular grafts. Some of the current issues engaging the division are: (l) life cycle projection for prosthetic heart valve components made of pyrolitic carbon; (2) preclinical test requirements for the totally implanted heart assist systems; (3) clinical testing protocols for physiologically responsive pacemakers; and (4) regulation of allograft heart valves.

3. Division of Clinical Laboratory Devices (DCLD)

The DCLD engaged in several important issues during FY 89. One issue involved the advent of the Clinical Laboratory Improvement Act of 1988 (CLIA '88) and its implementation implications on ODE/DCLD. Another issue involved development of policy relative to the handling of clinical in-vitro devices (IVDs) intended for non-traditional use settings.

With regard to CLIA '88, DCLD staff met with staff from the Health Care Financing Administration (HCFA) and the Centers for Disease Control (CDC) over the past few months to discuss various issues related to implementation of this Act and the possible roles each Public Health Service agency might have in providing technical assistance to HCFA.

In the area of non-traditional use IVDs (IVDs intended for use in malls, pharmacies, work places, etc.), DCLD was instru-

mental in working out a policy for administering these type of devices. The policy stipulates that IVDs previously cleared through the 510(k) process for traditional use settings, i.e., clinical labs, physicians' offices, etc., and proposed for use in non-traditional settings are both prescription devices and are substantially equivalent to each other providing there is no material difference in device performance specifications or labeling. The prescription device status confers an obligation on the manufacturers of these devices to comply with applicable state/local regulations relative to the definition of a licensed practitioner for those states in which the manufacturer intends to distribute the prescription IVD. If a manufacturer wishes to market a prescription device for home use, a 510(k) would be required and the new device may or may not be found substantially equivalent.

The past year also marked an increase in DCLD's involvement in the processing of PMAs utilizing DNA probe biotechnology. A PMA for Human Papilloma Virus (HPV) detection in cervical specimens was approved as an adjunct to the Pap smear in the identification of women at increased risk of developing cervical intraepithelial neoplasia and to aid the diagnosis of sexually transmitted HIV infections. In addition, DCLD cleared two 510(k)s for DNA probe devices: one for detection of Neisseria gonorrhea and the other for routine urine screening for bacteruria. A third 510(k) was cleared for a qualitative serum IVD for cholesterol to be used in a physician's office.

A hiring freeze during FY 89 precluded recruiting any new hires. The Division's medical and managerial expertise was

substantially affected with the departure of the Division's Director and medical officer who assumed the position of Associate Director, ODE.

4. Division of Gastroenterology/Urology and General Use Devices (DGGD)

For DGGD, FY 89 was characterized by changes in staff, the successful handling of a greatly increasing workload, and the management of several major problems and ongoing scientific and regulatory issues. Both Branch Chief positions were filled (one on an acting basis). A medical officer, two scientific reviewers, and the Division Director's secretary were hired. The most intense and immediately evident increase in DGGD's workload involved the review of over 1500 510(k)s for examination gloves submitted in response to FDA's revocation of the 510(k) exemption for these products. With the support of five reviewers detailed from other offices, the General Hospital and Personal Use Devices Branch reviewed and responded to these 510(k)s in a timely fashion. The efforts of these staff members, and the support given by the 510(k) Document Mail Center, cannot be overstated. The DGGD also saw an increase in the number and complexity of submissions on a number of different product lines. Many DGGD resources were devoted to supporting and defending the review of a 510(k) from Clark Research, Inc. which became the subject of litigation and Congressional and other inquiries.

Significant products cleared for marketing in FY 89 included the first balloon dilatation catheter for benign prostatic hypertrophy (BPH) and an organ storage and preservation solution. Considerable DGGD resources were devoted to

review of applications for biliary lithotripsy, hyperthermia for treatment of BPH, extracorporeal columns, and drug administration systems.

The DGGD's increased interactions with the professional and clinical community included work with the American Gastroenterological Association in their development of a position on biliary lithotripsy, and with the National Electrical Manufacturer's Association's newly-formed lithotripsy section's development of a joint protocol to study lithotripsy and hypertension. Increased DGGD interaction with The Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research reflected ongoing and new drug/device and biologic/device issues.

5. Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices (DOED)

The DOED has dealt with numerous public health and policy issues during FY 89. Two issues involved dental devices. High failure rates of temporomandibular joint (TMJ) implants, by one manufacturer, were reported. As a result, DOED convened a Dental Products Panel meeting to obtain a classification recommendation and to allow public airing of opinion by experts in the field. The other dental device issue concerned endosseous implants. DOED is preparing a 515(b) calling for PMAs for endosseous implants. A detailed PMA guidance was developed after inspections revealed that this industry was generally unaware of FDA requirements for scientific data to support a PMA.

Other ongoing issues within DOED have been the review of diagnostic ultrasound devices, in particular the review of fetal Doppler ultrasound instrumentation. An OB-GYN Devices Panel meeting on August 29, 1988, endorsed two indications for use of fetal Doppler ultrasound, i.e., cardiac evaluation (fetal cardiac chambers and great vessels) and intrauterine growth retardation evaluation. The Panel met again in January 1989 to discuss the issue. As a result of those meetings and meetings with industry and clinical groups, a decision was made to 510(k) fetal Doppler ultrasound. Due to be released this Fall is an updated 510(k) diagnostic ultrasound guide with an added section on fetal Doppler ultrasound.

Two other areas of intense activities within DOED have been contraceptive devices and home uterine monitoring devices (HUMDs). Neither of the two pre-Amendments barrier contraceptive devices, the glans cap and the intravaginal pouch, had been previously classified. Both types of barrier contraceptives were recommended for Class III by the OB-GYN Devices Panel on March 7, 1989. ODE agrees with the panel and is proceeding to prepare necessary documents to classify these devices. In addition, a 515(b) regulation will be promulgated for the glans cap. DOED is preparing premarket testing guidelines for female barriers with the potential to prevent sexually transmitted diseases.

Panel meetings and lengthy discussions with manufacturers and other outside interests regarding the intended use of HUMDs have been held. At present, discussion continues on whether or not HUMDs can detect preterm labor as a stand-alone device separate from nursing services.

In the staffing area, a Deputy Director was hired for DOED. This will enable DOED to streamline procedures and policy decisions. As a result of appointing the new Deputy Director, a vacancy occurred in the position of branch chief of the Ear, Nose and Throat Devices Branch.

6. Division of Ophthalmic Devices (DOD)

The DOD has had several major public health and policy issues which came to conclusion during FY 89. These include two issues relating to contact lenses: the use of homemade saline solutions and the recommendations surrounding the use of extended wear contact lenses. As for homemade salines, revised indications for use and new and improved warnings and directions for use were issued. Letters to manufacturers and public health announcements through press releases, magazine articles and interviews were used to disseminate the information.

The extended wear contact lens usage issue concluded with an interim agency position on the wearing time for these lenses to reduce the recommended times for wear to a maximum of 7 days from the previous 30 days between removal for cleaning and disinfection. This determination was made based on review and analysis of a national study on incidence and risk factors of ulcerative keratitis associated with extended wear contact lenses as well as an in-depth review of available data bases both from within and outside the agency.

Another area of intense activity has been in the intraocular lens area where the adjunct phase-out plan for IOL investigations has entered its third and final phase of a three year plan. This

third phase of the program has generated a bolus of premarket approval applications that were submitted at the end of the calendar year 1988 which put a tremendous strain on the existing resources within the Division. To deal with this problem, a special team of individuals were assembled to take a close look at the PMA review process for IOLs. As a result, several policy statements have issued this fiscal year.

DOD was able to fill the Deputy Director's position, a position which was vacant for over three years. This enabled DOD to improve its policy development capabilities, and restructure its priorities for office management.

Because of the hiring freeze during FY 89, no new hires were made in the scientific review area. Some individuals left during this period which put an additional strain on available resources in DOD. Nevertheless, a high productivity rate was maintained.

7. Division of Surgical and Rehabilitation Devices (DSRD)

The DSRD has had several major public health and policy issues which were prominent in FY 89. Two major issues were related to surgery devices: the reclassification of old suture materials and the cancer threat associated with mammary implants.

Six reclassification petitions for old suture materials were filed and processed through the advisory panel which agreed with the proposals to reduce the classification of these materials from class III to class II. During FY 89, we reclassified gut and vicryl suture materials. Nylon, polypropylene, dacron,

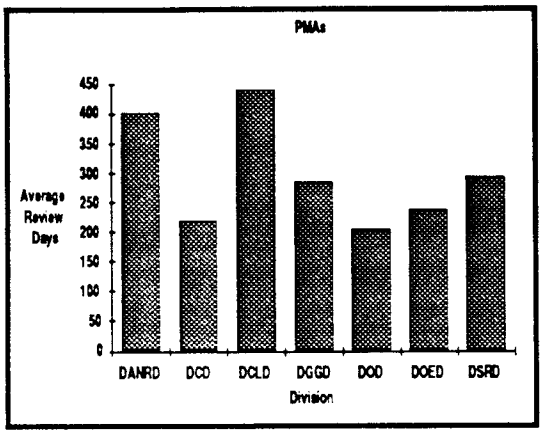
and silk materials are in the final stage of review. We also made determinations on protests and reconsideration petitions on these reclassification proposals.

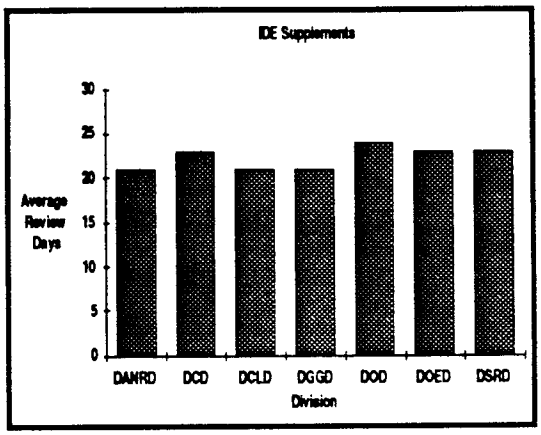
Dow Corning, the major manufacturer of silicone materials, informed DSRD of the results from a rat bioassay for silicone gel. The study showed a significant increase in solid state sarcomas, which indicated a potential health risk to 2 million women who are currently implanted with these devices. All offices of the Center were involved in responding to this issue. First, assessment of the level of risk presented by these data was resolved through intense review and consultation with experts from other FDA centers, the National Institutes of Health, the National Center for Toxicological Research, and other government agencies. Information was then released to the public through talk papers and through open discussions with plastic surgeons, the Health Research Group, and numerous women advocacy groups at a General and Plastic Surgery Advisory Panel meeting on November 22, 1988. In addition to this effort, we plan to call for PMAs for Silicone Gel Filled Breast Implants. Most of the test requirements have already been shared with the industries involved in these products through meetings and other public forums. DSRD has also worked extensively with the Center's Office of Training and Assistance, as well as the State of Maryland, in the development of educational materials for new recipients of these devices.

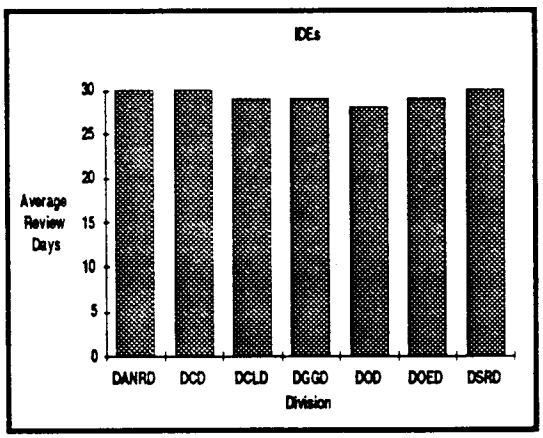
During this year DSRD lost seven employees and has rehired two. This high rate of attrition has had an adverse impact on work performance.

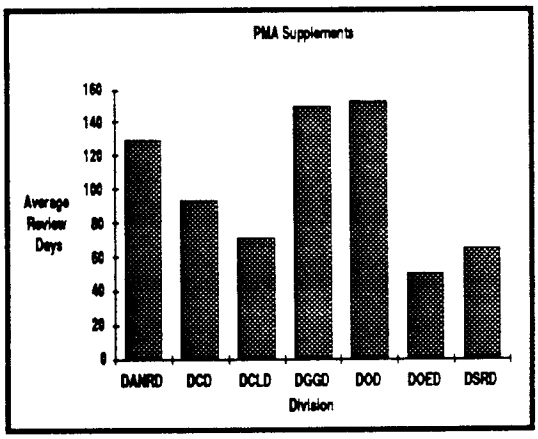
C. DIVISION PERFORMANCE DATA

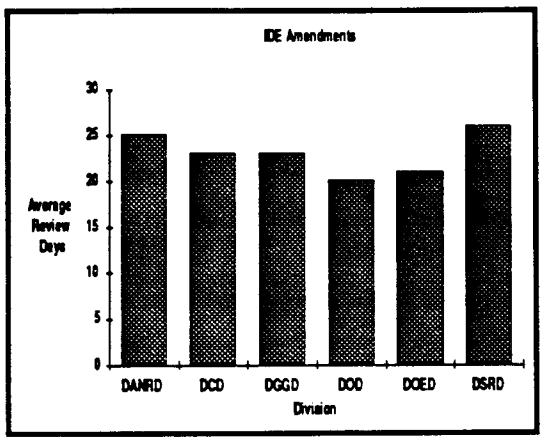
CHART 20 - Average FDA Review Time for Major Submissions by ODE Division FY 89











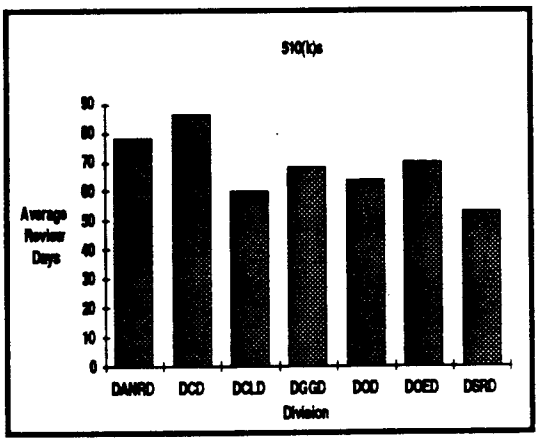
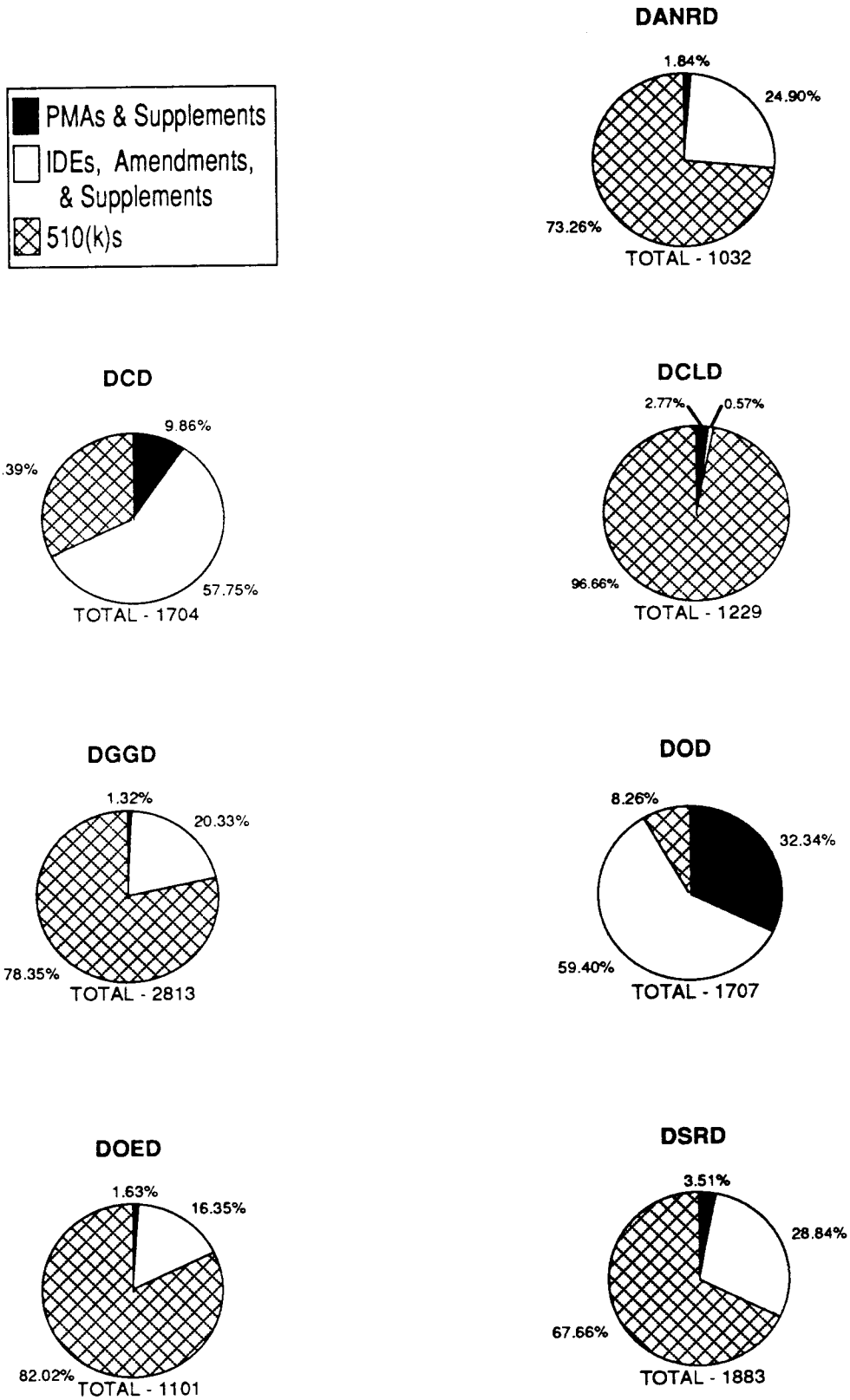


CHART 21 - Major Submissions Received by ODE Division FY 89



VI. OFFICE MANAGEMENT

A. ORGANIZATIONAL STRUCTURE

ODE is comprised of seven divisions grouped according to medical specialty: cardiovascular devices; anesthesiology, neurology, and radiology devices; surgical and rehabilitation devices; gastroenterology/urology and general use devices; obstetrics/gynecology, ear, nose, throat, and dental devices; clinical laboratory devices; and, ophthalmic devices. In addition, two offices report directly to the ODE director: the Program Management Office, an administrative office, and the Program Operations Staff, which coordinates the review of PMAs, IDEs, and 510(k)s.

There were major changes at the highest level of ODE management during this fiscal year. In July of 1989, Mr. Robert L. Sheridan, the Deputy Director of ODE who had been serving as Acting Director since June of 1988, was appointed the Director of ODE and is currently serving in that capacity. Also Dr. David L. West, formerly ODE Associate Director, and Dr. Jerome A. Donlon, formerly Director of ODE's Division of Clinical Laboratory Devices, were named as Deputy Director and Associate Director, ODE, respectively.

B. TRAINING

In FY 89, ODE continued its vigorous support of training. A total of $114,938 was spent in this area, an increase of $10,099 over FY 88. Throughout the year, employees participated in coursework directed towards advanced degrees, courses in office automation, supervisory training, seminars on research and emerging technolo-

gies relating to medical devices, courses at local universities, and continuing education at professional meetings.

C. OFFICE AUTOMATION

ODE continues to pursue an aggressive program of providing office automation equipment for use by its employees. Major activities in office automation included the procurement and installation of hardware and software, training of users, participation in the feasibility study for the redesign of the ODE Tracking Systems, and connecting additional users to the Center's VAX through the Ethernet system.

Due to the large number of device applications received each year and the need to prepare numerous review documents, ODE purchased additional equipment as a tool to process the applications as quickly as possible. Office automation is a high priority for ODE management and will continue to be a high priority in the future.

1. Hardware and Software

The majority of the hardware and software ordered in FY 88 was received during the 1st and 2nd quarter of FY 89. ODE received 69 AST 286 personal computers, 71 Fujitsu printers, a DEST scanner for the DECmate and a DEST scanner for the IBM compatible or Apple Macintosh computer. Most of the equipment was installed during the second quarter.

During FY 89 ODE submitted requisitions amounting to over $98,000 for additional hardware and software. ODE received 7 AST 386 personal computers, 8 Hewlett-Packard Laser Jet

Chart 22 - ODE Computer Hardware Status
FY 88 - FY 89

HARDWARE	On Hand in FY 88	Received in FY 89	On Hand in FY 89
DECmate II Word Processors	55	0	55
DECmate III Word Processors	35	0	35
LQPO2 Letter Quality Printers	30	1	31
LQPO3 Letter Quality Printers	6	0	6
LA50 Draft Quality Printers	38	0	38
LA75 Draft Quality Printers	39	0	39
LA100 Draft Quality Printers	7	0	7
LA210 Draft Quality Printers	2	0	2
LNO3 LASER Printers	21	2	23
VT220 Terminals	42	1	43
VT320 Terminals	7	0	7
PRO 350 Terminals	4	0	4
Ricoh FAX 1000L	1	0	1
CP/M Boards for DECmates	67	0	67
Electrohome Projectors	1	0	1
Compaq 286 PCs	11	0	11
Fujitsu Draft Printers	10	60	70
Macintosh Plus/SE PCs	5	0	5
Apple Laserwriter Printers	4	1	5
Apple Imagewriter Printers	1	0	1
HP Laser Jet II Printers	0	8	8
AST 286 PCs	0	69	69
AST 386 PCs	0	7	7
Fujitsu Letter Quality Printers	0	11	11
DEST DECmate Document Scanners	0	1	1
DEST PC Document Scanners	0	1	1

II printers, 2 Digital Equipment Corporation LN03 laser printers, 1 Apple Laserwriter NT printer, and software and hardware for existing equipment.

With the purchase of the additional personal computers in FY 89, ODE achieved its goal of a 1:1 ratio between a computer terminal capable of word processing and an ODE employee that could and would use such equipment.

2. Tracking Systems

Individuals responsible for the ODE tracking system functions participated in interviews conducted by the Office of Information Systems as part of a feasibility study to redesign the ODE tracking systems. These individuals provided suggested changes and additional data requirements for the new integrated tracking system. The ODE Basic Tracking System and the Division Tracking System will be combined into one information system using the Oracle relational database management system.

3. Telecommunications - Ethernet

All of the AST 286 computers have been connected to the CDRH Ethernet system. Individuals operating these computers can participate in the electronic mail system which links computer terminals, word processors, personal computers and mainframe computers within the Center. PC users can also access a translation program on the VAX to convert WordPer-

fect documents into Digital Equipment Corporation WPSPLUS word processing documents for use by individuals with DEC terminals. This process can also be reversed.

4. Document Transfer and Conversion

With the introduction of the new IBM compatible personal computers ODE reviewers can accept diskettes containing draft copies of documents (like summaries of safety and effectiveness) typed in WordPerfect to help speed the preparation of the final documents. Completed documents can be transferred to the DECmate through the conversion program on the Center's VAX for final document preparation.

In addition, ODE installed an optical character reader for the IBM compatible PC and one for the DECmate. With these devices, typed documents are scanned and transferred to magnetic media. This process eliminates the retyping of documents and also reduces preparation time.

5. New Facsimile Machine

To accommodate the needs of ODE employees, ODE installed a Ricoh FAX 1000L and ordered an additional Ricoh FAX 1000L. This plain paper facsimile machine routinely sends and receives documents to/from other Center components and other Government agencies. Periodically, ODE communicates with private industry; however, FAX communication is not a formal mechanism for industry/ODE correspondence. A hard copy for all IDE, 510(k), PMA and reclassification

petition correspondence remains the official form of document submission to ODE. Likewise, while ODE may FAX a copy of the Agency response to the industry submission, the official copy is always sent via U.S. Mail. The use of the facsimile machine in communicating with the regulated industry remains for the convenience of the government.

6. Voice Mail

The Director and Acting Deputy Director now have Voice Mail accounts on the FDA Voice Mail System. This system allows them to communicate with the Director, CDRH and other registered users on the system.

7. Optical Storage and Retrieval System

Plans are progressing for the introduction of optical disk technology within ODE. In FY 90, ODE plans to upgrade some of its IBM compatible personal computers to access the CDRH optical disk system.

8. Computer Training

Training in the use of office automation equipment continues to receive emphasis as more individuals gain access to computer terminals, word processing equipment and personal computers. During FY 89, 13 employees received basic DECmate word processing training and 10 employees received advanced DECmate word processing training. In addition, 76 employees were trained in the use of WordPerfect

5.0, which is the word processing software used on the new personal computers.

Training was also provided in the All-in-1 system on the VAX. Twenty-two employees were trained in All-in-1 basics and 9 employees received advanced All-in-1 training.

Several employees were trained to search databases. Seven employees were trained in Grateful Med, a software package used on a PC to formulate a literature search prior to accessing the National Library of Medicine MEDLINE database. Six employees were trained in NURSESEARCH, a software package used on a PC to formulate literature search strategies in preparation for a search of the Cumulative Index to Nursing and Allied Literature. Finally, 3 employees learned to search CDRH databases.

VII. 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.]

Table 1. PMA/IDE/510(k) Submissions Received
FY 85 - FY 89

Type of Submission	No. Received				
	FY 85	FY 86	FY 87	FY 88	FY 89
Premarket Approval:					
Original Applications	97	69	81	96	84
Amendments	597	853	748	754	856
Supplements	393	478	700	727	810
Amendments to Supplements	628	714	871	919	999
Reports for Orig. Applications	236	297	514	535	466
Reports for Supplements	132	174	162	59	57
Master Files	23	36	43	41	32
PMA Subtotal:	2,106	2,621	3,119	3,131	3,304
Investigational Device Exemptions:					
Pre-original Applications	21	20	15	8	7
Original Applications	204	206	218	268	241
Amendments	366	275	265	311	271
Supplements	2,457	2,884	2,836	3,391	3,038
IDE Subtotal:	3,048	3,385	3,334	3,978	3,557
Premarket Notification:					
Original Notifications	5,254	5,063	5,265	5,536	7,022
Supplements	1,800[a]	2,050	2,113	2,713	3,752
510(k) Subtotal:	7,054	7,113	7,378	8,249	10,774
PMA/IDE/510(k) Total:	12,208	13,119	13,831	15,358	17,635

a/ Estimate based on incomplete data.

Table 2. Original PMAs
FY 85 - FY 89

Action	FY 85	FY 86	FY 87	FY 88	FY 89
Number received	97	69	81	96	84
Number of final approvals	37	72	46	46	56
Average review time (days) for final approvals:[a]					
FDA	347	395	337(257)	262(142)	247(145)
Non-FDA	43	44	81 (27)	75 (17)	101 (42)
Total	390	439	418(284)	337(159)	348(187)
Number under review at end of period:[b]					
Active[c]	103	63	50	48	62
(Active and overdue)	N/A	(16)	0	(1)	(24)[e]
On hold[d]	60	72	77	66	52
Total	163	135	127	114	114[f]

N/A - Not available.

a/ Average review times in parentheses are calculated under the Premarket Approval of Medical Devices Regulation (21 CFR Part 814).

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

c/ FDA responsible for processing application.

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

e/ This total includes 7 applications for IOLs.

f/ This total includes a large number of IOL applications received just before the end of calendar year 1988.

Table 3. PMA Supplements
FY 85 - FY 89

Action	FY 85	FY 86	FY 87	FY 88	FY 89
Number received	393	478	700	727	810
Number of final approvals					
"Panel track"[a]	7	9	8	9	13
Others	370	468	557	643	506
Total	377	477	565	652	519
Average review time (days) for final approvals:[b]					
FDA	240	186	148(138)	124 (95)	122(109)
Non-FDA	8	10	11 (5)	25 (12)	41 (31)
Total	248	196	159(143)	149(107)	163(140)
Number under review at end of period:[c]					
Active[d]	306	249	224	195	364
(Active and overdue)	N/A	(107)	0	(2)	(62)[f]
On hold[e]	80	54	120	107	167
Total	386	303	344	302	531[g]

N/A - Not available.

a/ Supplements requiring 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.

b/ Average review times in parentheses are calculated under the Premarket Approval of Medical Devices Regulation (21 CFR Part 814).

c/ 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.

d/ FDA responsible for processing application.

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

f/ This total includes 46 applications for IOLs.

g/ This total includes a large number of IOL applications received just before the end of calendar year 1988.

Table 4. Original IDEs
FY 85 - FY 89

Action	FY 85	FY 86	FY 87	FY 88	FY 89
Number received	204	206	218	268	241
Number of decisions					
Approved (%)	59(29)	58(27)	60(27)	79(30)	89(36)
Not approved (%)	128(64)	138(65)	153(68)	172(66)	143(58)
Other (%)[a]	14 (7)	17 (8)	11 (5)	9 (3)	13 (5)
Total	201	213	224	260	245
Average FDA review time (days)[b]	37	35(28)[c]	28	27	29
Percent (%) of decisions made within 30 days[b]	82	91(93)[c]	97	99	100
Number under review at end of period[d]	24	17	11	19	16
Number overdue at end of period[b]	4	0	0	0	0

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

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

c/ FY 86 performance reflects completion of 4 applications that were already overdue when FY 86 began. Excluding these applications from the analysis yields an average review time of 28 days and 93% of decisions made within 30 days.

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 5. IDE Amendments
FY 85 - FY 89

Action	FY 85	FY 86	FY 87	FY 88	FY 89
Amendments received[a]	365	274	265	316	271
Decisions on amendments					
Approved(%)	186(52)	192(58)	132(52)	170(52)	127(45)
Not approved(%)	77(21)	61(18)	71(28)	88(27)	78(28)
Other(%)[b]	98(27)	77(23)	51(20)	68(21)	75(27)
Total	361	330	253	327	280
Average FDA review time (Days)[c]	51	99	33	24	23
Percent of decisions made within 30 days[c]	67	74	96	98	99
Average approval time (Days) for IDEs with amendments					
Total time[d]	160	169	152	152	176
FDA time	N/A	N/A	83	65	68
Non-FDA time	N/A	N/A	69	87	108
Amendments under review at end of period	75	19	31	20	11
Amendments overdue at end of period[c]	56	2	0	0	0

N/A - Not available.

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

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

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

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

Table 6. IDE Supplements
FY 85 - FY 89

Action	FY 85	FY 86	FY 87	FY 88	FY 89
Number received	2,457	2,884	2,836	3,391	3,038
Number of decisions	2,190	3,599[a]	2,784	3,405	3,023
Average FDA review time (days)[b]	33	116(21)[c]	22	22	22
Percent (%) of decisions made within 30 days[b]	78	72(90)[c]	95	99	99
Number under review at end of period[d]	854	139	175	157	170
Number overdue at end of period[b]	728	0	0	0	0

a/ These decisions include approximately 1,000 intraocular lens IDE supplements, the majority of which had been pending for a significant period of time when FY 86 began and which were reviewed by a special team assigned to eliminate this backlog; without these reviews, the FY 87 and FY 86 review rates are comparable.

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

c/ FY 86 performance reflects completion of 728 applications that were already overdue when FY 86 began. Excluding these applications from the analysis yields an average review time of 21 days and 90% of decisions made within 30 days.

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 7. 510(k)s
FY 85 - FY 89

Action	FY 85	FY 86	FY 87	FY 88	FY 89
Number received	5,254	5,063	5,265	5,536	7,022
Number of decisions:					
Substantially equivalent	4,491	4,388	4,105	4,432	4,867
Not substantially equivalent	132	98	103	82	92
Other[a]	472	873	784	999	1,177
Total	5,095	5,359	4,992	5,513	6,136
Percent (%) not substantially Equivalent[b]	2.8	2.2	2.1	1.8	1.9
Average review time(days):[c]					
Total time[d]	76	72	69	78	82
FDA time[e]	N/A	66	56	64	66
Percent (%) of decisions made within 90 days[c], based on:					
Total time[d]	68	65	71	67	70[g]
FDA time[f]	N/A	93[h]	96	99	99
Number under review at end of period:[i]					
Active[j]	N/A	733	934	913	1,270
(Active and overdue)[c]	N/A	(25)	0	0	0
On hold[k]	N/A	308	409	445	989
Total	1,337	1,041	1,343	1,358	2,259[l]

N/A - Not available.

a/ Includes withdrawals, deletions, and other administrative actions.

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

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

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

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

f/ 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)).

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

(Continued on next page.)

Table 7. 510(k)s
FY 85 - FY 89

(Continued from previous page.)

h/ Based on final 2 quarters only.

i/ Historical problems in the previous 510(k) data system currently prevent us from obtaining completely accurate information on the number of 510(k)s under review. The numbers above are the most accurate available at this time.

j/ FDA responsible for processing notification.

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

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

Table 8. Major Submissions Received
FY 80 - FY 89

Type of Submissions	Fiscal Year 1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
Original PMAs	62	60	90	76	65	97	69	81	96	84
PMA Supplements	165	259	277	360	435	393	478	700	727	810
Original IDEs	71	237	189	189	203	204	206	218	268	241
IDE Supplements	460	924	1,694	1,750	3,077	2,457	2,884	2,836	3,391	3,038
510(k)s	3,167	3,684	3,798	4,477	5,004	5,254	5,063	5,265	5,536	7,022
Total Submissions	3,925	5,164	6,048	6,852	8,784	8,405	8,700	9,100	10,018	11,195

Table 9. Major Submissions Reviewed
FY 80 - FY 89

Type of Submissions	Fiscal Year 1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
Original PMAs	24	32	49[a]	46	43	37	72	46	46	56
PMA Supplements	78	239	238	327	243	377	477	565	652	519
Original IDEs	63	232	189	187	198	201	213	224	260	245
IDE Supplements	N/A	N/A	N/A	N/A	N/A	2,190	3,599[b]	2,784	3,405	3,023
510(k)s[c]	2,908	3,381	3,256	3,162	4,262	5,095	5,359	4,992	5,513	6,136
Total Reviews	3,073	3,884	3,732	3,632	4,746	7,900	9,720	8,611	9,876	9,979

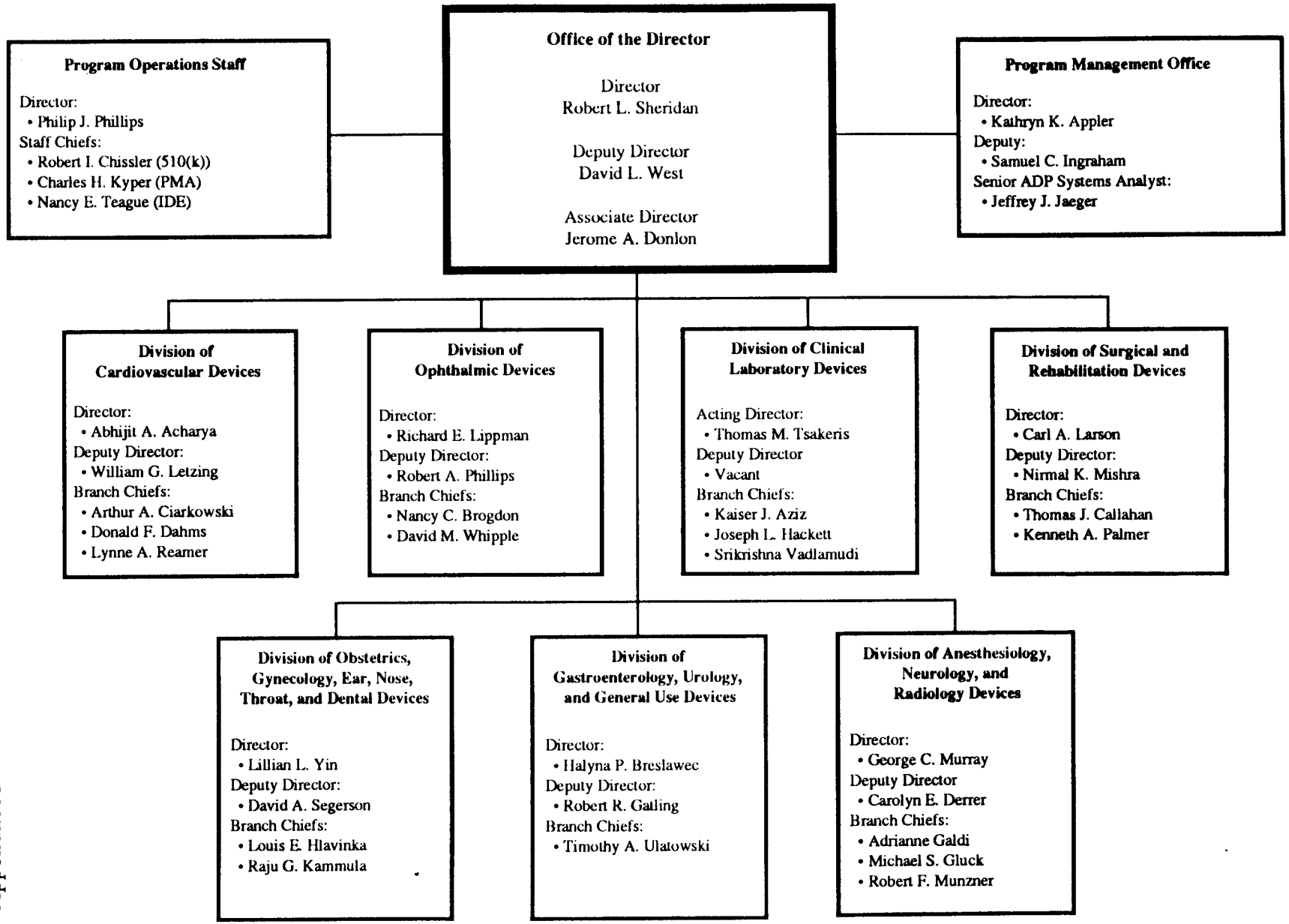
N/A - Not available.

a/ Includes one denial of approval.

b/ These decisions include approximately 1,000 intraocular lens IDE supplements that had been pending for a significant period of time when FY 86 began and which were reviewed by a special team assigned to eliminate this backlog; without these reviews, the FY 87 and FY 86 review rates are comparable.

c/ Data for FY 80-84 does not include withdrawals and deletions.

OFFICE OF DEVICE EVALUATION



Appendix A

ODE STAFF ROSTER
FY 1989

OFFICE OF THE DIRECTOR

DeMarco, Carl
Donlon, Jerome
Noel, Linda
Robinson, Mary Jo
Sheridan, Robert
Trissler, Patsy
West, David

PROGRAM MANAGEMENT OFFICE

Appler, Kathryn
Cavanaugh, Sharon
Evans, Sylvia
Hanlon, Helen
Ingraham, Sam
Jaeger, Jeff
Leonard, Christina
Murphy, Kathleen
Taylor, Delores
Trammell, Dennis
Vaughan, Sharyn
Wall, Barbara

PROGRAM OPERATIONS STAFF

Allen, Gene
Alonge, Laura
Bagley, Tammy
Calhoun, Elizabeth
Chissler, Robert
Clingerman, Angela
Davis, Lisa
Dillard, Sharon
Dorsey, Leslie
Falls, Deborah
Fisher, Lisa
Hlavinka, Louis
Huff, William
Jackson, Barbara
Kyper, Charles
Lewis, Jessica
Parker, Mervin
Perticone, Diane
Phillips, Philip
Rosecrans, Heather
Shepherd, Lois
Shorter, LeVonne
Shulman, Marjorie
Stringer, Stanley
Sutton, William
Teague, Nancy
Tran, Thanh
Yaffe, Leah

DIVISION OF ANESTHESIOLOGY, NEUROLOGY, AND RADIOLOGY DEVICES

Bradley-Allen, Cheryl
Dawson, John
Derrer, Carolyn
Dillard, James
Frost, Kathleen
Galdi, Adrianne
Gantt, A. Doyle
Glass, John
Gluck, Michael
Grenier, Alice
Harrison, Maria
Hinckley, Stephen
Hollander, Julie
Keely, G. Levering
Kirschenmann, Pamela
Koustenis, George
Lundsten, Kathy Poneleit
McCarthy, Elizabeth
Minear, Diane
Munzner, Robert
Murray, George
Porter, Barbara
Shuping, Ralph
Smallwood, Senora
Tran, Ann
Trinh, Hung
Withiam-Wilson, Marcia
Wolf, Beverly
Zaremba, Loren
Zier, David

DIVISION OF CLINICAL LABORATORY DEVICES

Alpert, Arnold
Appell, Raynor
Atwood, Pamela
Aziz, Kaiser
Brindza, Larry
Bucher, Betty
Chace, Nina
Cricenti, Patricia

Drumming, Warrena
Fugate, Kearby
Hackett, Joseph
Huff, LaVerne
Hull, Makita
Jones, Doris
Moore, Nancy
Nutter, Cathy
Poole, Freddie
Rahda, Edappallath
Rechen, Katherine
Rooks, Cornelia
Selfon, Nathaline
Sellman, Viola
Staples, Broden
Stewart, Willard
Strongin, Wendy
Temel, Seniye
Tsakeris, Thomas
Vadlamudi, Srikrishna

DIVISION OF
CARDIOVASCULAR DEVICES

Abel, Dorothy
Acharya, Abhijit
Astor, Brad
Cheng, James
Ciarkowski, Arthur
Coleman, Yvette
Cromwell, S. Christina
Dahms, Donald
Danielson, Judith
Hwang, Shang
Kennell, Lisa
Kramer, Mark
Lemperle, Bette
Letzing, William
Loew, William
Lusted, Keith
McKenna, Joyce
Michaloski, Cathleen
Paulson, Kirsten
Reamer, Lynne
Rosile, Nadine
Roy, Joydeb
Ryan, Tara
Shanker, Rhona
Shein, Mitchell
Scheppan, Jeanette
Sliwiak, Joan
Terry, Doris
Watson, Cassandra

DIVISION OF GASTROENTEROLOGY/
UROLOGY AND GENERAL USE
DEVICES

Acker, Rita
Bolden, Brenda
Breslawec, Halyna
Buas, Connie
Casciani, Francis
Conklin, Glenn
Fike, Robert
Gatling, Robert
Hubbard, Ruth
Mattan, Amalie
Melvin, Marsha
Mills, George
Moore, Shirley
Neuland, Carolyn
Nimmagadda, Rao
Park, James
Pfister, Richard
Rohrer, Susanne
Rubendall, Rita
Scudiero, Janet
Seiler, James
Ulatowski, Timothy
Williams, Richard
Wong, Linh

DIVISION OF OBSTETRICS/
GYNECOLOGY, EAR, NOSE,
THROAT, AND DENTAL DEVICES

Bove', Celeste
Browne, Myra
Cunningham, Melody
Daenecke, Patricia
Ellerbe, Vanessa
Ferrante, Monica
Jasper, Susan
Jeffries, Melpomnei
Kammula, Raju
Kuchinski, Michael
Lamb, Joyce
Miller, Patricia
Pollard, Colin
Sands, Barry
Segerson, David
Sharpe, Ellsworth
Singleton, D. Gregory
Tsai, Miin-Rong
Turner, Margaret
Yin, Lillian
Yurawecz, Jane

DIVISION OF
OPHTHALMIC DEVICES

Batra, Karam
Brogdon, Nancy
Brown, Daniel
Burke-Nicholas, Marsha
Calogero, Don
Carbone, Josephine
Chen, Tzeng
Choy, Joanne

Chuang, Lin
Clark, Geoffrey
Cohen, Linda
Delotch, Patricia
Duvall, Anita
Felton, Eleanor
Gelles, Muriel
Gerondakis, Rose
Gouge, Susan
Jan, George
Jones, Susanna
Kapoor, C. Lal
Lewis, Debra
Lippman, Richard
Maurey, Karen
McCarthy, Denis
Pettinato, Mark
Phillips, Robert
Rogers, Donna
Saviola, James
Sloane, Walter
Storer, Patricia
Tilgman, Gwendolyn
Weiblinger, Richard
Whipple, David
Yoza, Alice
Zollo, Mary Jo

DIVISION OF SURGICAL AND REHABILIATATION DEVICES

Barnes, Roger
Berne, Bernard
Bhatnagar, Gopal
Blackwell, Michael
Bland, Marcella
Callahan, Thomas
Crossen, Kevin
Day, Stephen
Einberg, Elmar
Ferl, Janet
Ferl, James
Hamilton, Candace
Hastings, Robert
Hemeon-Heyer, Sheila
Howell, Heather
Kawin, Leslie
Larson, Carl
Luu, Hoan-My Do
March, Eduardo
McCuin, Sandra
McDermott, Kenneth
McGunagle, Daniel
Melkerson, Mark
Mishra, Nirmal
Moreland, Frances
Palmer, Kenneth
Parkhurst, L. John
Randolph, Joseph
Riegel, Elizabeth
Ruiz, Aida
Schroeder, Marie
Smith, Bettie
Smith, Gwendolyn
Starowicz, Sharon
Sternchak, Richard
Stevens, Theodore
Thomas, David C.
Thomas, David U.
Tilton, Paul
Torres-Cabassa, Angel
Trisler, Patsy
Walker, Kathleen