**OFFICE OF DEVICE EVALUATION**

# ANNUAL REPORT

**FISCAL YEAR 1995**

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

**Acknowledgements**

The PMA, IDE, and 510(k) staff offices, in conjunction with the Office of Information Systems, provided most of the data used in this report. Many staff members within the ODE Review Divisions and Program Management Office also made significant contributions of data and information. The report was prepared and edited by Cathy Hobbs and prepared by MaryAnn Gornick on desktop publishing equipment.

Carl T. DeMarco
Project Director

# Table of Contents

## *PREFACE*

*During Fiscal Year 1995, a major goal of the Office of Device Evaluation (ODE) was to respond to the challenge to be more efficient and productive in carrying out our review activities. As this report demonstrates, we've made significant progress in achieving these goals during this past fiscal year.*

*In the 510(k) program, we succeeded in virtually eliminating the 510(k) backlog (those with a cycle pending beyond 90 days). Only nine 510(k)s were overdue at the end of FY 95 compared to 460 in FY 94 and 1,894 in FY 93. We also reduced the average review time for 510(k)s by more than 24 percent--from 184 days in FY 94 to 137 days in FY 95. At the same time, one half of these devices were reviewed in 91 days or less.*

*In the PMA program, we cut by more than 50 percent the average time it took us to reach a final decision on a PMA after we received an evaluation from one of our advisory panels. This post-panel work -- which includes completing the review process, working out the labeling and, in some cases, inspecting the manufacturing facility -- was reduced from about 600 days in FY 94 to about 250 days in FY 95. In addition, we are meeting more frequently with firms, both prior to their submitting PMAs and afterwards, to discuss what we expect in the application, labeling, indications, etc. This should facilitate continued progress on PMA reviews. By the end of FY 95, we reduced the number of PMA supplements active and overdue from 110 to 49. ODE did this despite receiving 127 more PMA supplements in FY 95 than in the previous year.*

*As important as our 510(k) and PMA gains are, we are most heartened by two advances in the IDE program. Taken together, I believe they will enable sponsors to speed the clinical development of important new devices in the U.S. The first advance is that in the second half of FY 95, we approved 65 percent of IDEs on the first 30-day cycle; this compares with 49 percent during the first half of the year, and 30 percent in the previous fiscal year. This improvement is due, at least in part, to our recent emphasis on talking with manufacturers before the protocol is submitted and during the initial review. ODE staff held over 200 pre-IDE meetings with industry to discuss clinical trial strategies and potential IDE applications.*

*The second important advance in the IDE program concerns Medicare reimbursement for the use of certain devices not yet cleared/approved by FDA. We had a series of productive meetings with the Health Care Financing Administration (HCFA), and the result is a new rule which took effect November 1, 1995. Under this new rule, most IDE products will be categorized as "evolutionary" and, hence, eligible for Medicare payment. Under the agreement negotiated with HCFA, products designated as evolutionary are those belonging to a product type for which basic safety and effectiveness have already been established. Thus, although evolutionary devices will remain investigational under the Food, Drug, and Cosmetic Act, they can be regarded by HCFA as not experimental and, therefore, potentially covered.*

*None of these accomplishments would have been possible without the dedication and perseverance of a hard working staff. I congratulate the ODE staff on a job well done and encourage them to continue their exceptional work throughout the next fiscal year.*

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

# EXECUTIVE SUMMARY
# OFFICE OF DEVICE EVALUATION ANNUAL REPORT
# FISCAL YEAR 1995

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. Following are the highlights of ODE's activities for Fiscal Year 1995 (FY 95). These are explained more fully in the body of the report.

## Workload

During FY 95, ODE received 16,978 submissions, 73 more than were received in FY 94. The FY 95 total represents the second largest total number of submissions ever received during one fiscal year although it is in line with our experience in earlier fiscal years, with the exception of FY 92, when an exceptional number of submissions totaled 18,086.

On the output side, ODE completed the processing of 12,013 major submissions, an increase of 968 from the 11,045 major submissions reviewed during FY 94. This represents a three-year trend of increases in the number of major submissions reviewed.

## Resources

During FY 95, ODE ended the year with 362 employees on board. During the year, ODE lost 28 employees (16 scientific reviewers, 6 medical officers, and 6 support staff) through resignation or retirement. This attrition was offset by the addition of 32 new employees (20 scientific reviewers, 7 medical officers, and 5 support staff).

## Premarket Approval

During the fiscal year, we received 39 original PMAs, four less than the number received in FY 94. The total number of 249 PMA actions, down from 354 PMA actions last year, includes 55 filing decisions, 147 review activity determinations, and 47 approval decisions.

Twenty-seven PMAs received final approval, one more than the number of approvals in FY 94. Another 16 original PMAs were found to be approvable. PMAs found not approvable dropped from 18 last year to 4 and there were no denials issued during FY 95. In total, the number of PMA decisions declined from 66 last year and 47 this fiscal year.

Average FDA review time for original PMAs reaching final action decreased from 374 days in FY 94 to 276 days during FY 95. The non-FDA component of review time increased slightly from 78 days in FY 94 to 81 days this fiscal year. On balance, the combined average review time decreased from 452 days last year to 357 days in FY 95.

The total number of PMAs under review at the end of the fiscal year dropped for the third year in a row, from 139 to 125. The active PMAs under review at the end of this fiscal year remained stable at 69 compared to 67 last year, while those on hold decreased from last year, from 72 to 56.

During FY 95, the number of supplements received increased from last year's 372 to 499, reversing the trend of the last few years of decreasing numbers of PMA supplements. The total number of PMA supplement actions, which includes 5 panel track filing decisions, 151 review activity determinations, and 588 approval decisions, dropped to 744 from last year's 809 total actions.

**Investigational Devices**

We received 214 original IDEs during FY 95, a significant increase from the 171 received in FY 94. The same holds true for IDE decisions; 210 decisions were made on original IDEs in FY 95, an increase from 174 last year. Each fiscal year, the number of decisions made closely parallels the number of documents received, because of the short turn-around time for IDE reviews. The average FDA review time for original IDEs stayed essentially constant at 29 days in FY 95 as compared to 29 days last year. During FY 95, 92 percent of all original IDE decisions were issued within 30 days, down from 95 percent in FY 94. Of the total decisions made on original IDEs in FY 95, the percentage of decisions that resulted in approval rose significantly from 30 percent in FY 94 to 57 percent in FY 95.

During this fiscal year, 210 amendments were received, down from 254 during the last fiscal year. Decisions were made on 213 amendments: 106 approvals (50%); 38 disapprovals (18%); and 69 other administrative actions (32%). Ninety-two percent of these decisions were made within 30 days.

It took an average total time of 232 days to approve IDEs in FY 95, down from 242 days in FY 94. This average approval time consisted of 70 days for FDA time, down from 83 days last year, and 162 days for non-FDA time, up from 159 days in FY 94. Of the IDEs which were complete enough to permit substantive review, the percentage of IDEs approved on the first review cycle increased from 30 percent in FY 94 to 57 percent during FY 95. Furthermore, during the first six months of FY 95 this percentage was 49 percent and increased to 65 percent during the second half of the fiscal year.

**Premarket Notifications (510(k))**

During this reporting period, ODE received 6,056 original 510(k)s and 4,552 510(k) supplements. Original and supplemental 510(k)s totaled 10,608 submissions, a decrease of 397 from the 11,005 received in FY 94. The 7,948 total decisions rendered on original 510(k)s during FY 95 is an increase of 813 over FY 94 and represents a new all-time record of 510(k) reviews completed in a single year.

The total average review time declined from 216 days in FY 94 to 178 days for FY 95, and the FDA review time decreased to 137 days from 184 days in FY 94.

There were 2,450 510(k)s in inventory at the end of this fiscal year, which is another significant decrease from the 4,374 510(k)s that were in FY 94's end-of-year inventory. The number on hold declined from 1,960 at the end of FY 94 to 964 at the end of this year. Most important, at the end of this reporting period only 9 510(k)s were active and overdue as compared to 1,894 in FY 93 and 460 in FY 94.

**Major Program and Policy Initiatives**

During FY 95, we undertook various policy and program initiatives concerning the following topics:

- reimbursement recommendations for investigational medical devices
- performance goals for the IDE Program
- availability of investigational devices during the intervening period between completion of the clinical study and approval of the marketing application
- pilot program for third-party review of selected premarket notifications (510(k)s)
- 510(k)s for device modification
- use of International Standard ISO-10993, Biological Evaluation of Medical Devices

**Goals for FY 96**

In light of our present resources and workload, the ODE staff will strive to increase efficiency and scientific rigor in the premarket review process by improving review times, emphasizing timely completion of post-panel actions, increasing early interactions with industry, and empowering managers with more decision-making authority.

**Guidance for Industry and Reviewers**

The following list of 51 guidance documents includes those that were issued in FY 95 by the Office of Device Evaluation and its review divisions.

Office of Device Evaluation
- Use of International Standard ISO-10993.
- Goals and Initiatives for the IDE Program.
- Implementation of the FDA/HCFA Interagency Agreement.
- Availability of Investigational Devices.

Division of Cardiovascular, Respiratory, and Neurological Devices
- Coronary and Cerebrovascular Guidewire.
- Percutaneous Transluminal Coronary Angioplasty (PTCA) Package Insert Template.

Division of Clinical Laboratory Devices
- Human Chorionic Gonadotropin (hCG).
- Drugs of Abuse Assays.
- Primary, Secondary and Generic Reagents for Automated Analyzers.

Division of General and Restorative Devices
- Ceramic Ball Hip Systems.
- 510(k) Orthopedic Devices.
- Polyethylene in Orthopedic Devices.
- Femoral Stem Prostheses.
- Modular Implant Components.
- Acetabular Cup Prostheses.
- Spinal Fixation Device Systems.
- Submerged (Underwater) Exercise Equipment.
- Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles.
- Electromyograph Needle Electrodes.
- Exercise Equipment.
- Heating and Cooling Devices.
- Therapeutic Massagers and Vibrators.
- Powered Muscle Stimulators, Ultrasound Diathermy and Muscle Stimulators.
- Powered Tables and Multifunctional Physical Therapy Tables.
- Immersion Hydrobaths.
- Communications Systems and Powered Environmental Control Systems.
- Beds.
- Biodegradable Polymer Fracture Fixation Devices.

Division of Dental, Infection Control, and General Hospital Devices (formerly the DGRD Pilot Division)
- Dental Handpieces.
- Sharps Injury Prevention Feature Guidance.
- Short-Term and Long-Term Intravascular Catheter.
- Latex Medical Gloves.

Division of Ophthalmic Devices
- IOL PMA/IDEs.
- Multifocal IOL IDEs/PMAs.
- Contact Lens Care Products.
- PRK Laser IDEs/PMAs.

Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
- Benign Prostatic Hyperplasia.
- Mechanical Lithotriptors and Stone Dislodgers.
- Conditioned Response Enuresis Alarms.
- Condom Catheters.
- External Penile Rigidity Devices.
- Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter).
- Endoscopes Used in Gastroenterology and Urology.
- Penile Rigidity Implants.

Menstrual Tampon.
Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence.
Latex Condom.
Male Condoms Made from New Material.
Endoscopic Light Sources Used in Gastroenterology and Urology.
Urological Irrigation System and Tubing Set.
Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology.
Hysteroscopes & Laparoscopes, Insufflators & Other Related Instrumentation, Submission Requirements for a 510(k).

**Reclassification/Classification of Devices**

During the year, ODE exempted a total of 157 class I devices from premarket notification, reclassified surgeon's instruments used with cochlear implants from class III to class I, revoked the exemption of blood culture system devices, and withdrew the proposed exemption of 7 class I devices.

In addition, we proposed the reclassification of 112 devices from class II to class I and their exemption as well as the exemption of 12 additional class I devices from premarket notification. ODE also received panel recommendations to reclassify immunohistochemical stains and non-roller type cardiopulmonary bypass pumps from class III to class II.

**Classification of Unclassified Devices**

During the year, ODE classified Temporomandibular Joint Prostheses, Glans Condoms, and Transilluminators into class III. Futhermore, we received panel recommendations to classify contact lens cases and endoilluminators in class II; visual trainers in class I; apgar timers, lice removal kits and infusion stands in class I; general purpose disinfectants in class I; sterilants in class II; and bone filling and bone augmentation devices into class II and class III.

**PMAs for Pre-Amendments Devices**

ODE published final 515(b) rules for testicular prosthesis and cranial electrotherapy stimulator devices and published proposed 515(b) rules for mechanical/hydraulic urinary incontinence devices, endodontic heat sterilizers, OTC denture cushions or pads and OTC denture repair kits, and class III pre-amendment Group 1 devices. ODE also rescinded a final rule for replacement heart valve allografts.

**Performance Standards**

We published proposed rules to establish mandatory performance standards for electrode lead wires and infant apnea monitors.

**Panel Activities**

ODE held 28 panel meetings during FY 95 involving 40 meeting days. Each panel met at least once (three panels met three times). There were 13 formal training sessions held for new panel members. The Agency received valuable advice on a variety of medical devices such as tumor markers, excimer lasers, implantable defibrillators, lasers used in general surgery, and a device for extracorporeal removal of low density lipoprotein (LDL) to lower LDL cholesterol in patients with familial hypercholesterolemia.

Panel members are leading authorities in a broad range of medical specialties and have current experience in medical practice, teaching and/or research. Each panel has at least one consumer and one industry representative. Qualified female and minority representation is encouraged; currently females make up over a third of our membership and minorities almost 24%.

**ODE Integrity Program**

During FY 95, it was necessary to investigate integrity issues in more than 38 instances. Most cases necessitated data audits of premarketing submissions. Some of these integrity issues were based, in part, upon internal inconsistencies within the submission, scientifically implausible data, contradictory information provided by scientific/clinical researchers, data inconsistent with the scientific/professional literature, information provided by employees of the applicant, and information obtained from legal documents.

This year saw the issuance of four letters to medical device firms by the Center for Devices and Radiological Health pursuant to FDA's "Application Integrity Program" (AIP); formerly known as the "Fraud Policy." Under the AIP, the substantive review of all pending and future submissions by the firms to whom the AIP letters were issued is suspended until the firms undertake an internal audit and implement an acceptable corrective action plan.

On the other side of the coin, FDA removed AIP restrictions from one firm that had previously been sent an AIP letter. This firm had successfully implemented a corrective action plan and FDA now accepts and conducts substantive reviews of premarketing applications from the firm.

During FY 95, more than 37 ethics issues and conflicts of interest problems arose. Several of these questions involved claims by manufacturers that they were not receiving fair or equal treatment during the review process. Other issues involved the receipt by ODE staff of free training, travel expenses, meals, cash honoraria, and other things of value from persons outside the government. Some questions involved the acceptance of faculty appointments and participation in committee activities of professional associations.

This fiscal year, ODE, in conjunction with the Office of Compliance, prepared and conducted two seminars for Center staff entitled "RS Medical: A Case Study - Lessons Learned." The purpose of

this seminar was to explore the events leading up to major civil litigation in which FDA was found to be responsible for improper conduct in regulatory activities related to this firm.

**Freedom of Information Requests and Congressional Inquiries**

ODE staff received 1,378 FOI requests during FY 95 indicating a steady increase over the last three years (943 in FY 94, 976 in FY 93, and 1,052 in FY 92). Congressional interest in ODE programs continued to be strong during this fiscal year. Over the past year, ODE staff responded to 39 Congressional letters.

**Publications**

During FY 95, the Office of Device Evaluation cleared 6 abstracts and 7 manuscripts authored by ODE staff for publication in professional and scientific journals, and 17 presentations delivered by ODE staff at professional and scientific and trade association meetings.

**Program Management and Support**

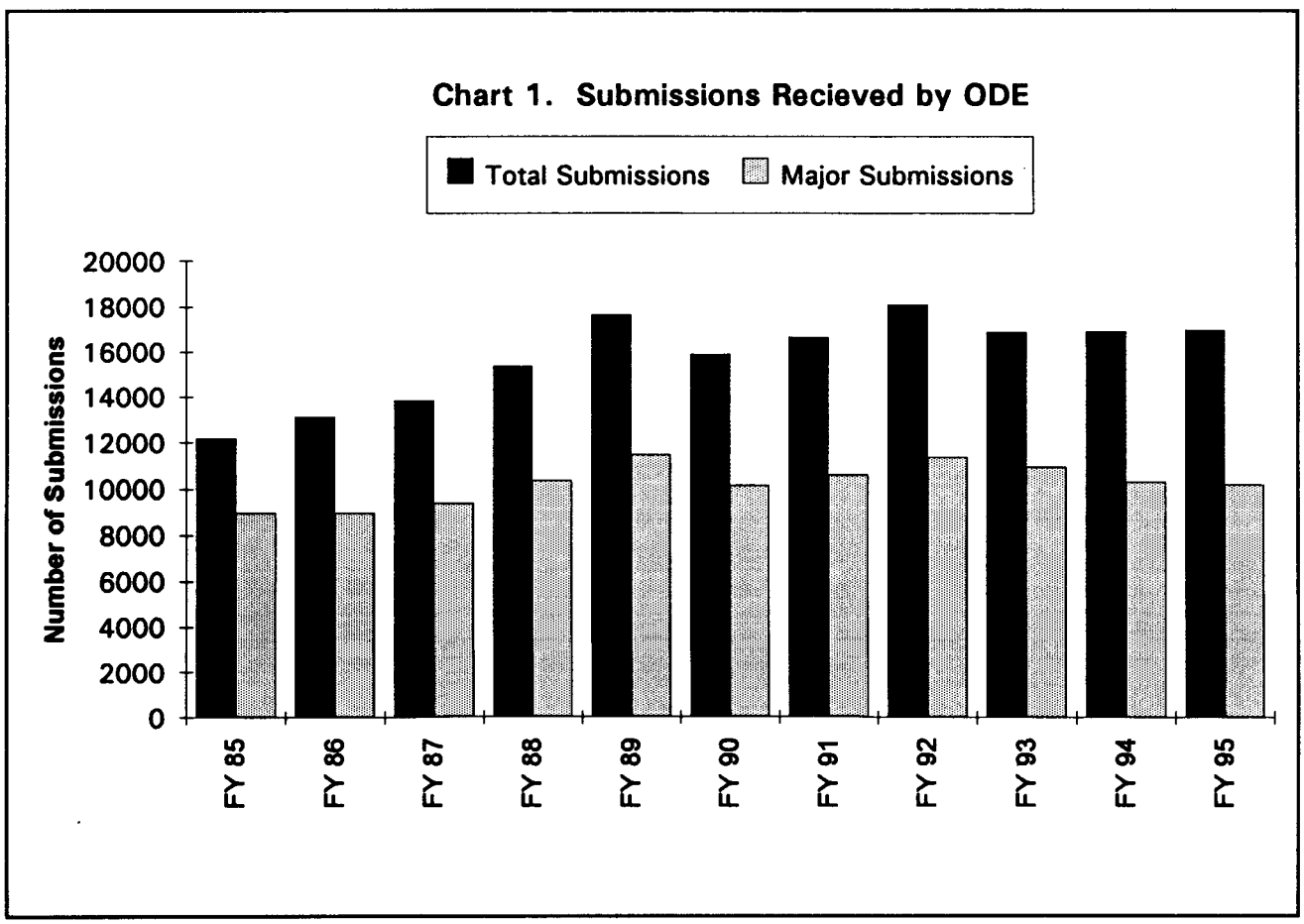
Professional development at all employee levels continued to be a vital segment of ODE's support activities in FY 95. ODE developed FY 94 training initiatives for major on-going staff development and industry outreach programs. ODE staff also participated in informational exchange meetings and seminars sponsored by health care associations, academia, other government agencies, consumer groups, etc., and with other Offices within CDRH in FY 95, such as the CDRH Scientific Roundtables and OSB Safety Conferences.

The ODE Program Management Office (PMO) continued to provide computer support to over 390 people within ODE and the contract document control service. The ODE effort to increase its computer capabilities was enhanced by the purchase of PCs, printers, software, and necessary upgrades for its existing base of equipment. ODE spent $249,000 on this effort in FY 95.

# ANNUAL REPORT
# OFFICE OF DEVICE EVALUATION
# FISCAL YEAR 1995

## I. INTRODUCTION

The Office of Device Evaluation (ODE) in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health is responsible for the program areas through which medical devices are evaluated and cleared for clinical trials and marketing. This report provides information about major programs administered by ODE during Fiscal Year 1995 (FY 95), October 1, 1994 through September 30, 1995. Part II below discusses the ODE workload and available resources, while Part III examines the performance and activities of the premarket approval, investigational device exemption, and premarket notification programs. Part III also contains comparative performance and trend analyses from previous fiscal years. Part IV covers procedural and policy issues and guidance documents and other management activities to further implement our policy and program goals and to streamline our procedures. This part also includes device reclassification, freedom of information, and PMAs for pre-amendments devices under Section 515(b). Part V covers various aspects of ODE resources. Finally, Part VI consists of statistical tables that contain the data on program performance for FY 95.



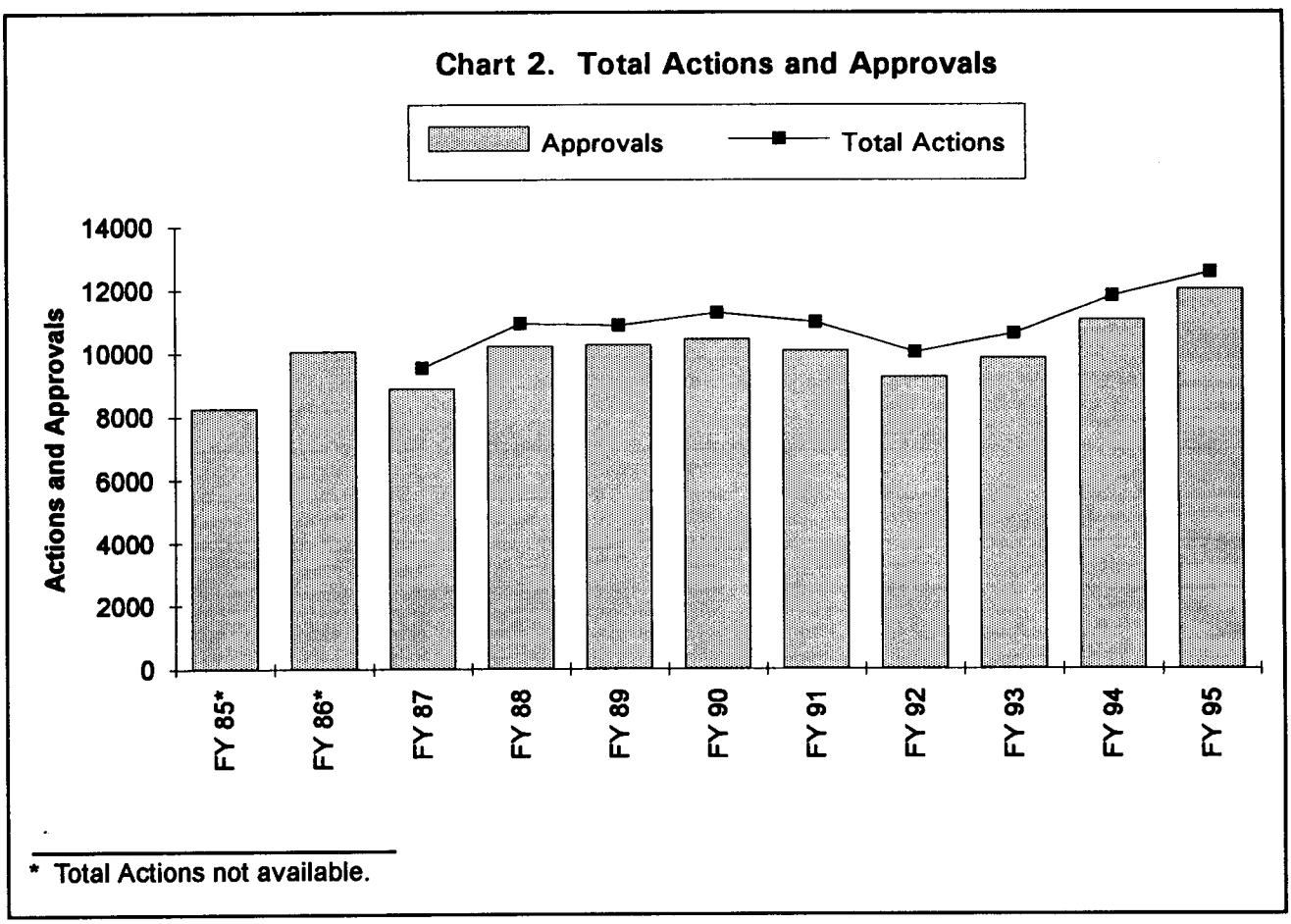
## II. OVERALL WORKLOAD AND RESOURCES

### A. Workload

During FY 95, ODE received a total of 16,978 submissions, 73 more submissions than were received in FY 94. The FY 95 total represents the second largest total number of submissions ever received during one fiscal year although it is in line with our experience in earlier fiscal years, with the exception of FY 92, when an exceptional number of submissions totaled 18,086.

The number of major submissions -- PMAs, PMA supplements, IDEs, IDE amendments, IDE supplements, and 510(k)s -- decreased in FY 95. We received a total of 10,189 major submissions, a decrease of 104 from the number of major submissions received in FY 94. This represents the third consecutive year in which there has been a decrease in the number of major submissions.

On the output side, ODE completed the processing of 12,013 major submissions, an increase of 968 from the 11,045 major submissions reviewed during FY 94. This represents a three-year trend of increases in the number of major submissions reviewed. In terms of output per reviewer,



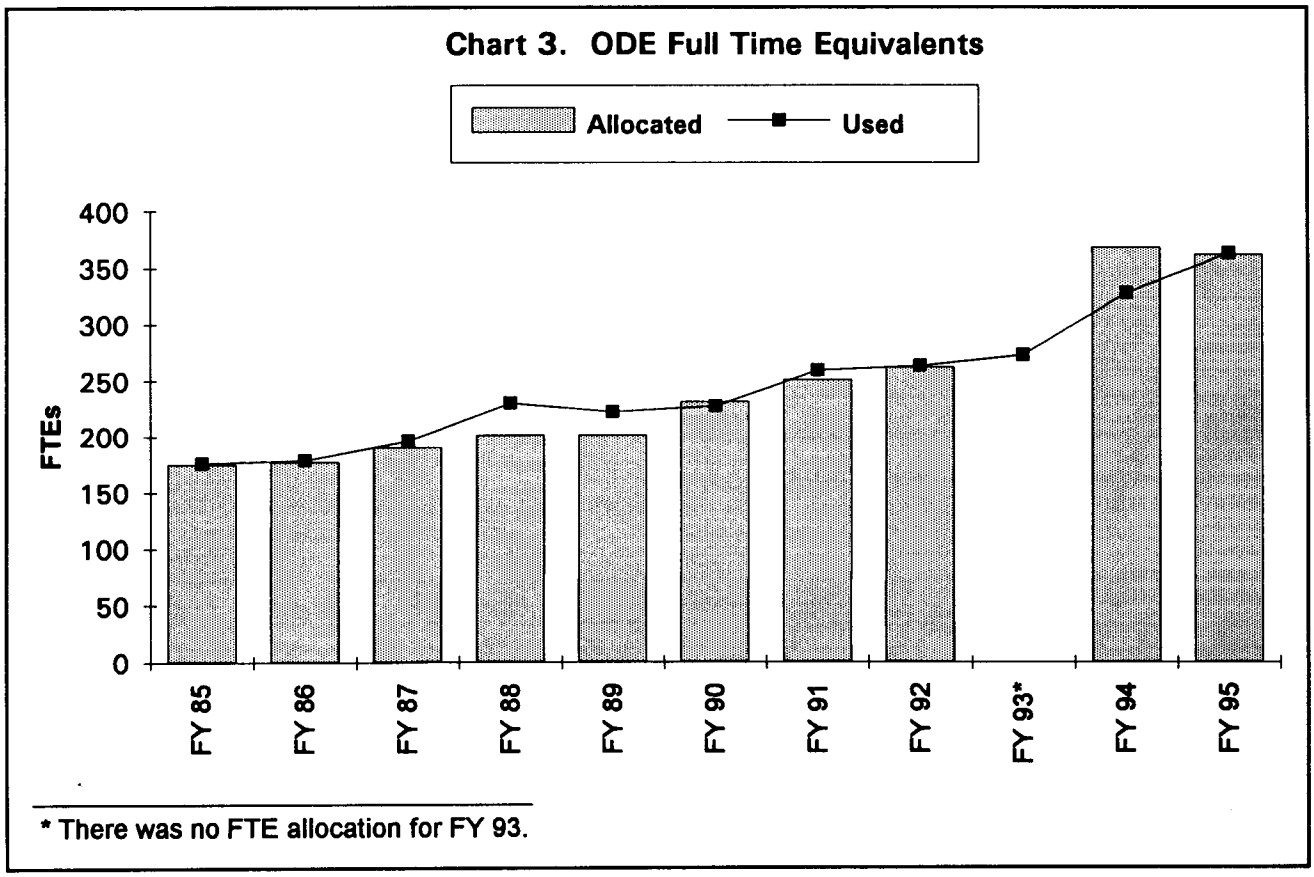
FY 95 is the second consecutive year in which the number of major submissions reviewed per full-time equivalent (FTE) has exceeded the number of submissions received per FTE.

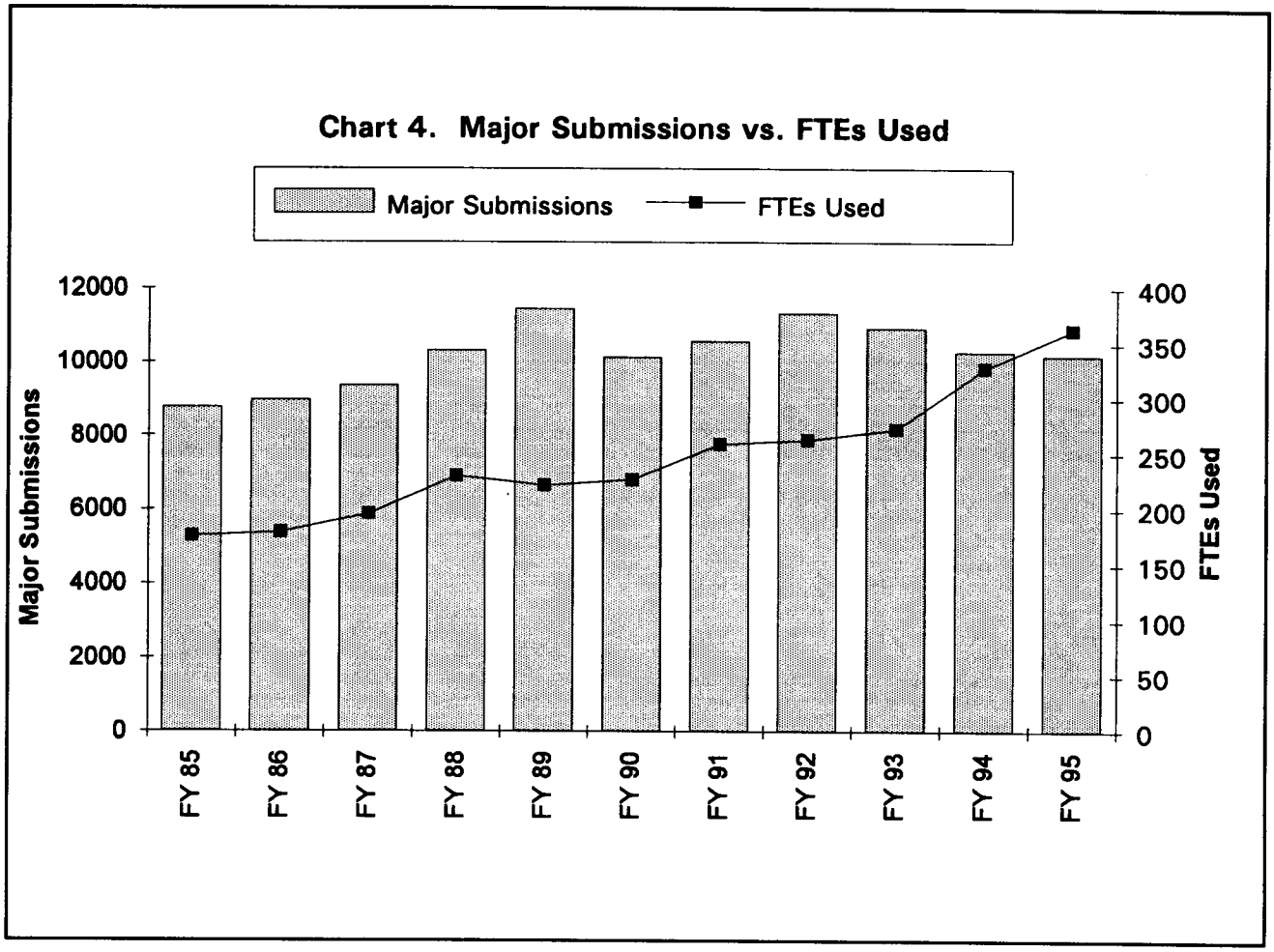
This recent increase in productivity is related in large part to program factors which have increased the efficiency of the review process and refined the processing of submissions. Many of these "management initiatives" were begun in FY 93 and are discussed in the FY 93 Annual Report. They include the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

**B. Resources**

During FY 95, ODE ended the year with 362 employees on board. During the year, ODE lost 28 employees (16 scientific reviewers, 6 medical officers, and 6 support staff) through resignation or retirement. This attrition was offset by the addition of 32 new employees (20 scientific reviewers, 7 medical officers, and 5 support staff).

The number of staff on board at the end of the fiscal year does not equal the number of full-time staff in ODE available throughout the fiscal year. The ODE staff available throughout the year is represented by the number of full-time equivalents (FTEs) actually used during the year. The






number of FTEs available to the program during the year are authorized through the budget process, which established an FTE ceiling of 362 FTEs for ODE. Because hirings were taking place throughout the year, the actual FTEs used during this fiscal year were 363.

In FY 95 ODE moved into new offices at 9200 Corporate Boulevard, Rockville, Maryland 20850. The move was scheduled for the beginning of the fiscal year in order to minimize the impact of the move on the processing of applications. FDA announced in two notices in the *Federal Register* of October 14, 1994, page 52170, and November 29, 1994, page 60992, that from October 7, 1994 through October 21, 1994 (14 calendar days), ODE would continue to accept mail but would not officially receive investigational device exemption applications, nor continue its review of such pending submissions, and that the statutory review periods on pending submissions would be suspended during this 14-day period needed for the relocation. However, FDA did officially accept premarketing submissions during this "14 day moving period" but added 2 weeks to the due dates of IDEs only because of their short 30-day turn-around time. This is reflected in the percent of decisions made within 30 days for approved IDEs and amendments.

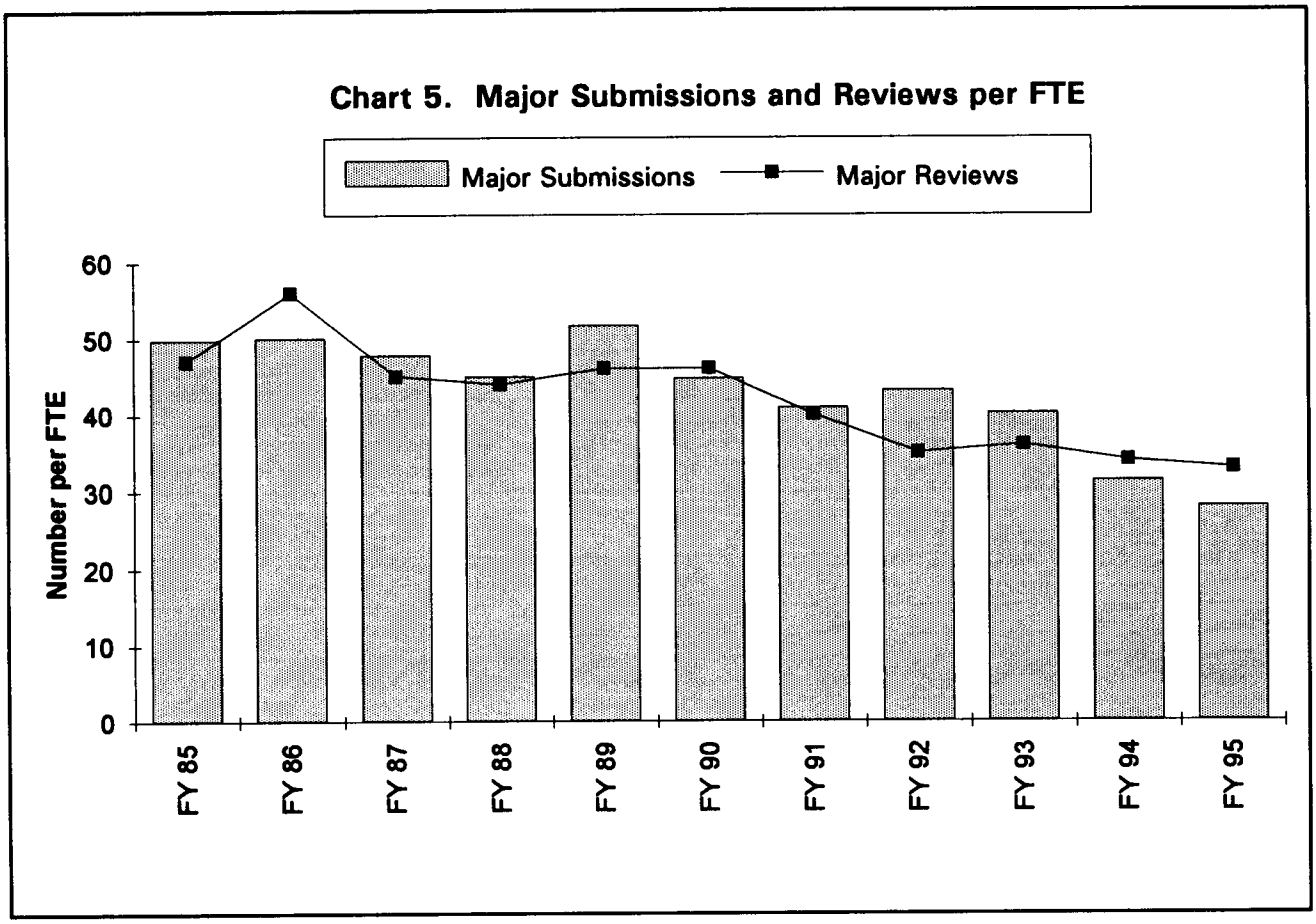


Chart 5. Major Submissions and Reviews per FTE
Major Submissions
Major Reviews
Number per FTE
60
50
40
30
20
10
0
FY 85
FY 86
FY 87
FY 88
FY 89
FY 90
FY 91
FY 92
FY 93
FY 94
FY 95

## III. MAJOR PROGRAM ACTIVITIES AND PERFORMANCE

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

### A. Premarket Approval

1. Premarket Approval Applications (PMAs)

Under the Federal Food, Drug, and Cosmetic Act (the Act) and the FDA regulations, *Code of Federal Regulations, Title 21* (the Regulations), a manufacturer or others must submit a PMA for

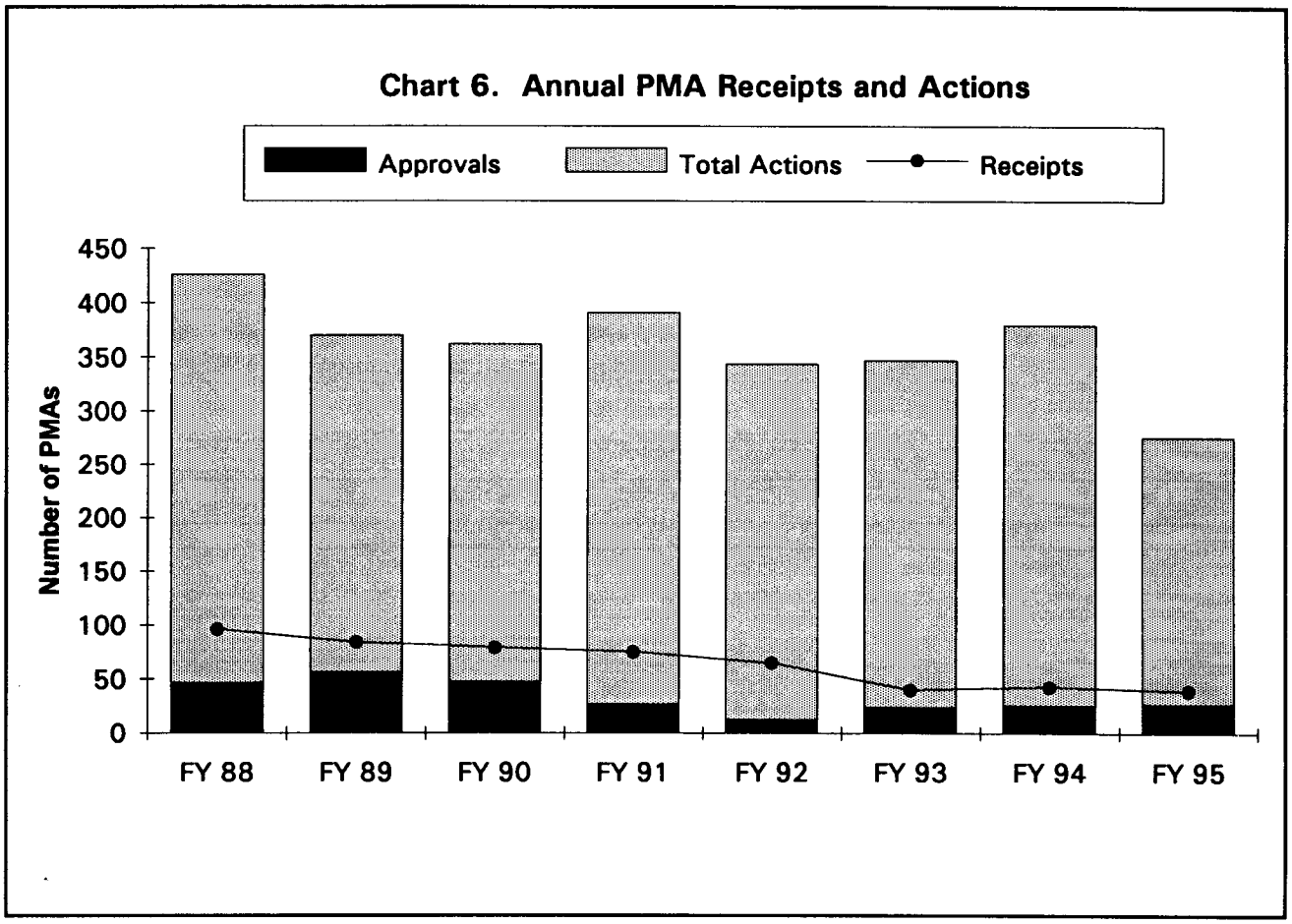
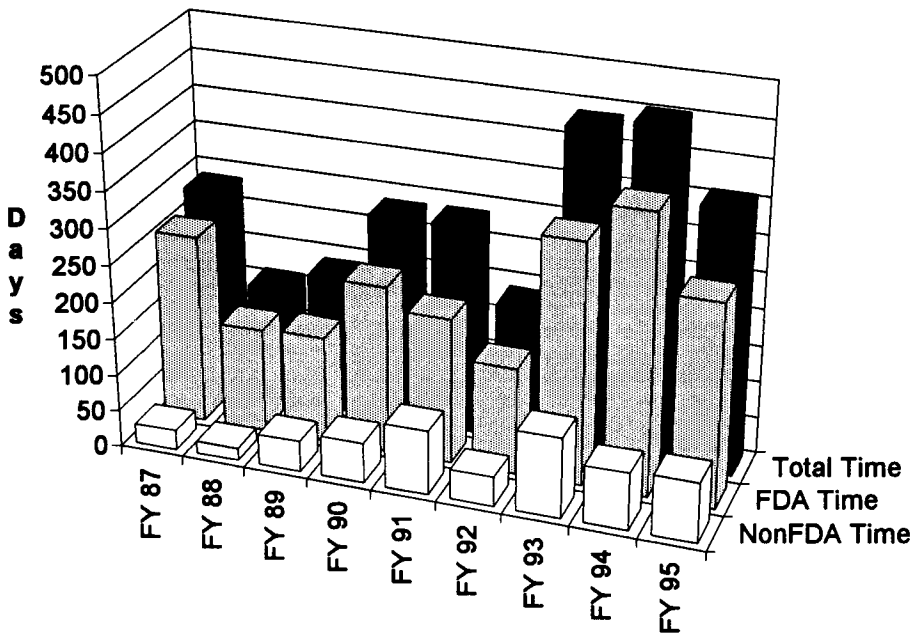


**Chart 7. Average Review Time for PMA Approvals**




FDA review and approval before marketing certain new Class III devices. The PMA must provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufactured in accordance with current good manufacturing practices. As part of the review process, FDA may present the PMA to an expert advisory panel for its recommendations. After obtaining the panel recommendations, the agency makes a determination to approve the PMA, deny it, or request additional information. If the PMA is approved or denied approval, FDA must publish a notice in the *Federal Register* to inform the public of the decision and make available a summary of the safety and effectiveness data upon which the decision is based. This publicly available summary does not include proprietary data or information submitted by the applicant.

During this fiscal year, we received 39 original PMAs, four less than the number received in FY 94. The total number of 249 PMA actions, down from 354 PMA actions last year, includes 55 filing decisions, 147 review activity determinations, and 47 approval decisions.

Twenty-seven PMAs received final approval, one more than the number of approvals in FY 94. Another 16 original PMAs were found to be approvable. PMAs found not approvable dropped

from 18 last year to 4 and there were no denials issued during FY 95. In total, the number of PMA decisions declined from 66 last year and 47 this fiscal year.

Prior to enactment of the 1986 PMA regulation, 21 CFR 814, PMA review times were calculated in accordance with practices in effect at that time. Those review times were referred to as "elapsed time". The PMA regulation's new procedures necessitated a new method for calculation of PMA review times. Time calculated under the new PMA regulation is termed "review time". After the enactment of this regulation, ODE continued to report both of these review times for purposes of continuity and to provide a basis for comparison. This dual reporting of review times has been maintained for over five years and the annual report now contains a sufficient number of reporting periods for "review time" under the PMA regulation to provide an historical basis for comparison. In last year's annual report, we stated that "elapsed time" will no longer be reported and, accordingly, it is not included in this report.

Average FDA review time for original PMAs reaching final action decreased from 374 days in FY 94 to 276 days during FY 95. The non-FDA component of review time increased slightly

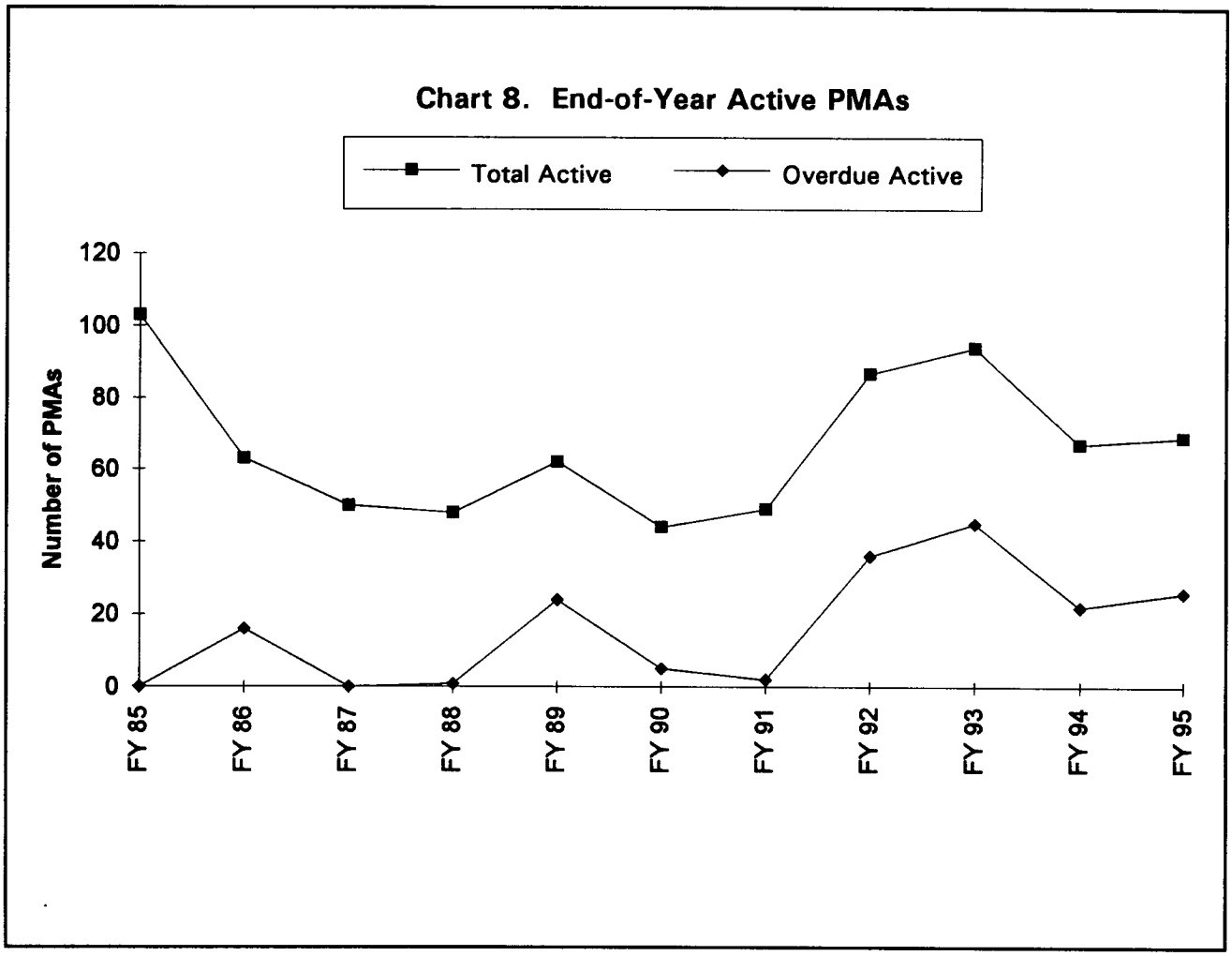
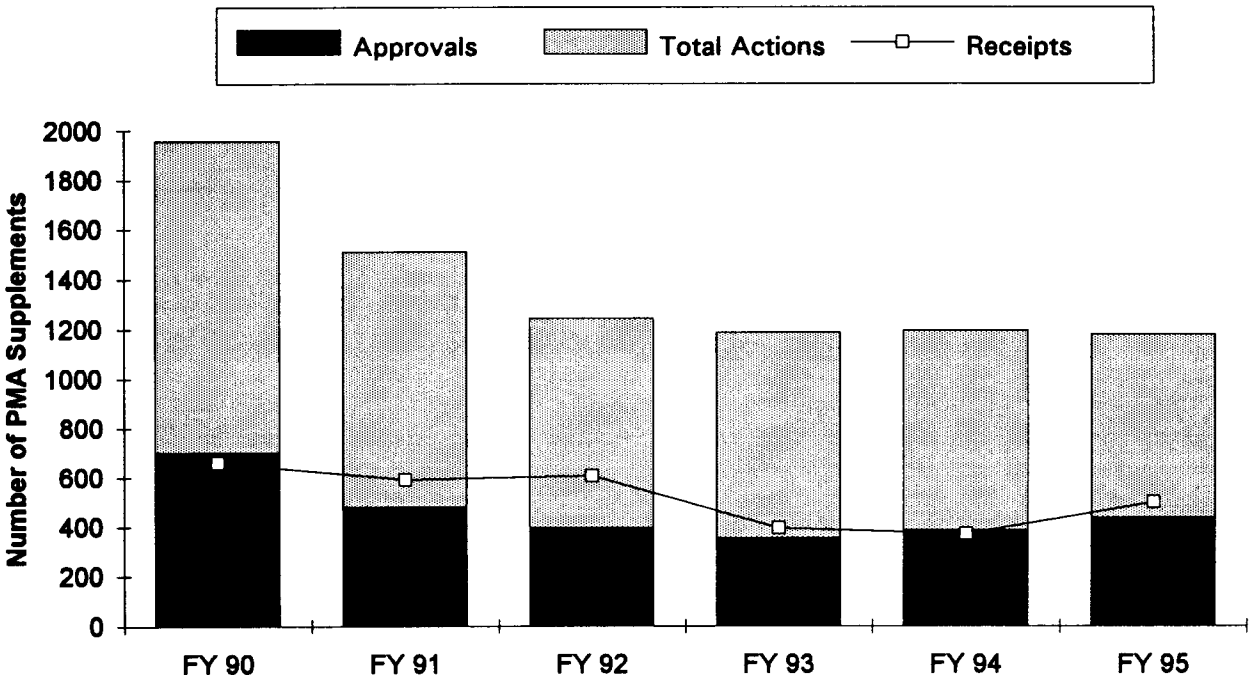


**Chart 9. Annual PMA Supplement Receipts and Actions**



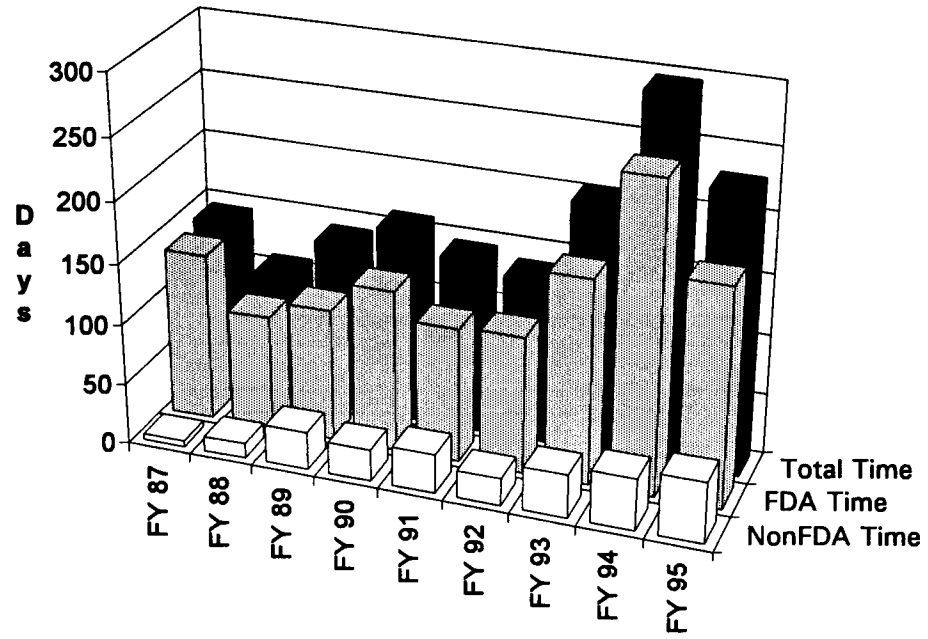

from 78 days in FY 94 to 81 days this fiscal year. On balance, the combined average review time decreased from 452 days last year to 357 days in FY 95.

The total number of PMAs under review at the end of the fiscal year dropped for the third year in a row, from 139 to 125. The active PMAs under review at the end of this fiscal year remained stable at 69 compared to 67 last year, while those on hold decreased from last year, from 72 to 56. The number of PMAs that were active and overdue increased slightly from 22 last year to 26 at the end of FY 95.

## 2. PMA Supplements

After a PMA is approved, the PMA holder may request FDA approval of changes to be made; for example, actual changes to the device, its labeling or packaging, or the manufacturing processes

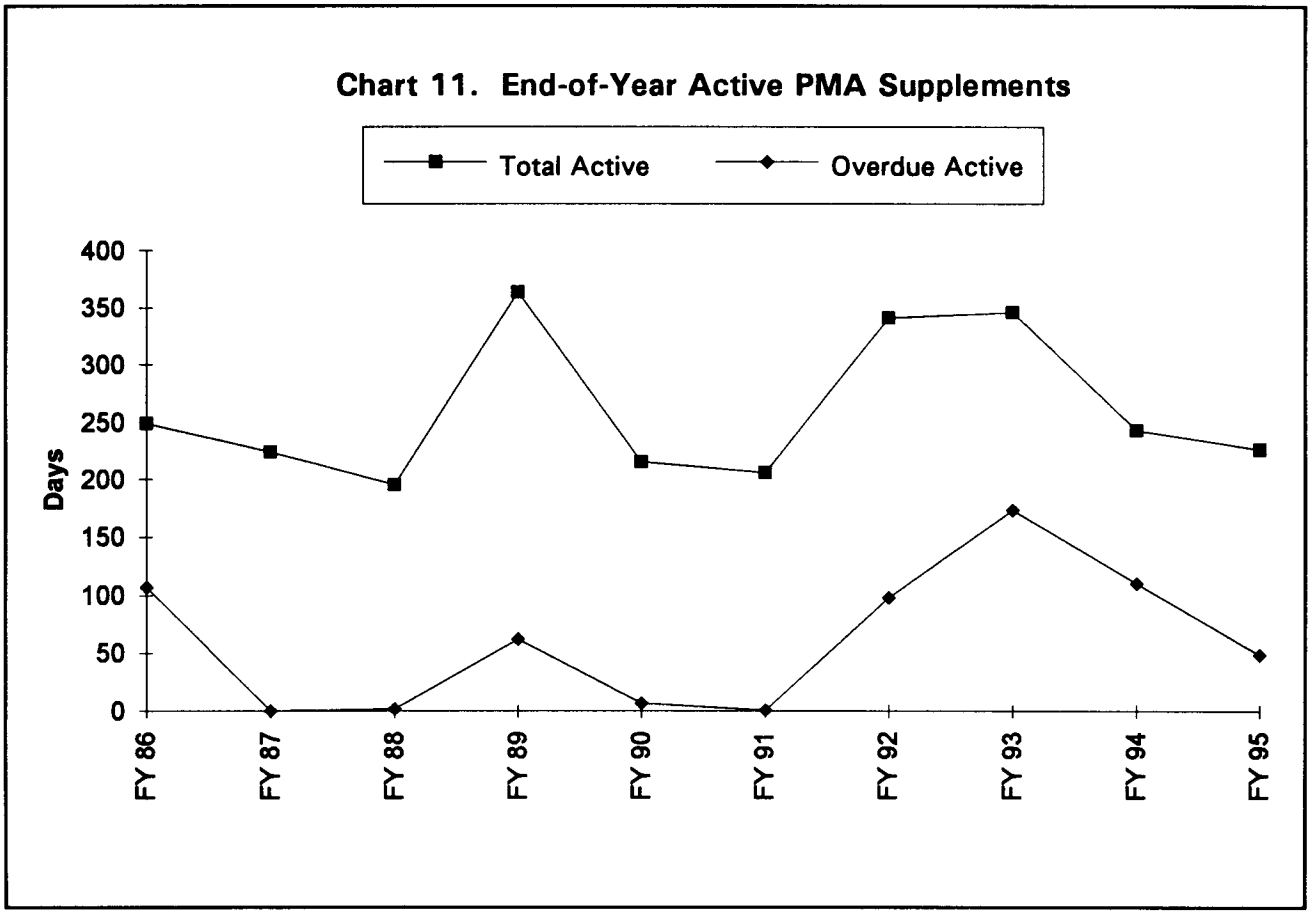
**Chart 10. Average Review Time for PMA Supplements**




used in its production. Unless prior approval is expressly not required by the PMA regulation, changes that affect the safety or effectiveness of the device require FDA premarket approval. FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology. Many PMA supplements are as complex as an original application.

During FY 95, the number of supplements received increased from last year's 372 to 499, reversing the trend of the last few years of decreasing numbers of PMA supplements. The total number of PMA supplement actions, which includes 5 panel track filing decisions, 151 review activity determinations, and 588 approval decisions, dropped to 744 from last year's 809 total actions.

A total of 435 PMA supplements were approved for marketing and included three panel track approvals. These approvals included three "panel track" supplements. Panel track supplements require the full administrative procedures normally associated with original PMAs, i.e., panel review, preparation of a summary of safety and effectiveness data, and publication of a *Federal Register* notice.




The FDA average review time for PMA supplements decreased from 253 days in FY 94 to 179 days this year; combined FDA and non-FDA review time decreased from 295 days last fiscal year to 228 days by the end of this year. The non-FDA time increased slightly from 42 days in FY 94 to 49 days in FY 95.

The total number of PMA supplements under review at the end of this year remained stable at 377 compared to 376 supplements under review at the end of FY 94. The number of PMA supplements that were active and overdue dropped considerably from 110 at the end of the last fiscal year to 49 at the end of this year. The number of active supplements was further reduced to 226 from 243 last year but the number of supplements on hold rose from 133 to 151 at the end of FY 95.

## B. Investigational Devices

### 1. Investigational Device Exemptions (IDEs)

Under the Act and Regulations, an individual, institution or company may sponsor the clinical investigation of a medical device to establish its safety and effectiveness. Before conducting a clinical trial, however, the sponsor must obtain the approval of an institutional review board (IRB) as well as informed consent from the study subjects at the time of their enrollment in the study. If the investigational device study presents a significant risk to the subjects, the sponsor also must obtain FDA's approval of an "investigational device exemption" application (IDE) under 21 CFR 812. The IDE must contain information concerning the study's investigational plan, report of prior investigations, device manufacture, IRB actions, investigator agreements, subject informed consent form, device labeling, cost of the device, and other matters related to the study. FDA has 30 calendar days from the date of receipt of the application to approve or disapprove an IDE submission.

We received 214 original IDEs during FY 95, a significant increase from the 171 received in FY 94. The same holds true for IDE decisions; the 210 decisions made on original IDEs during FY 95 increased from 174 last year. Each fiscal year, the number of decisions made closely parallels the number of documents received because of the short turnaround time for IDE reviews. The average FDA review time for original IDEs stayed essentially constant at 29 days in FY 95 as

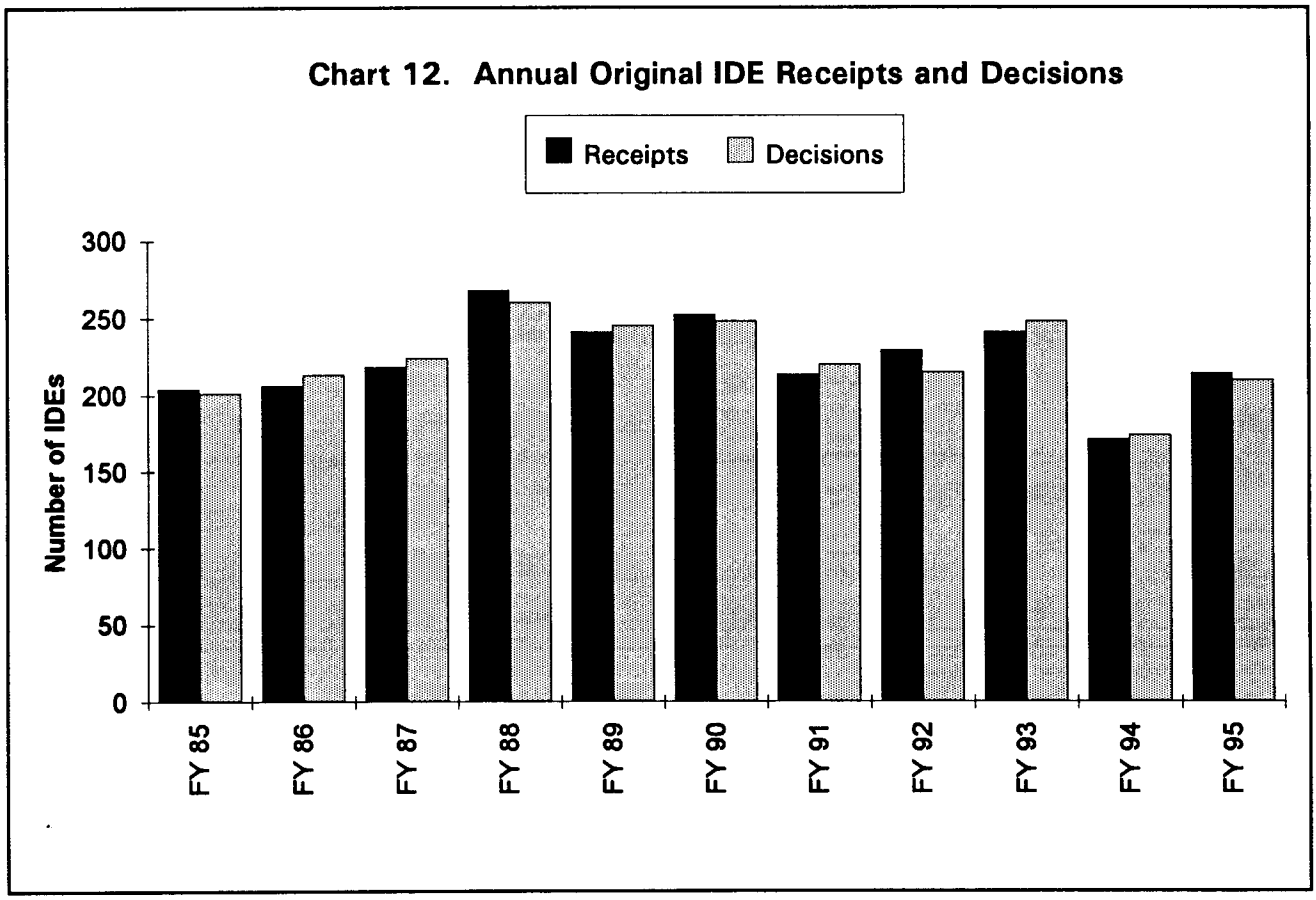
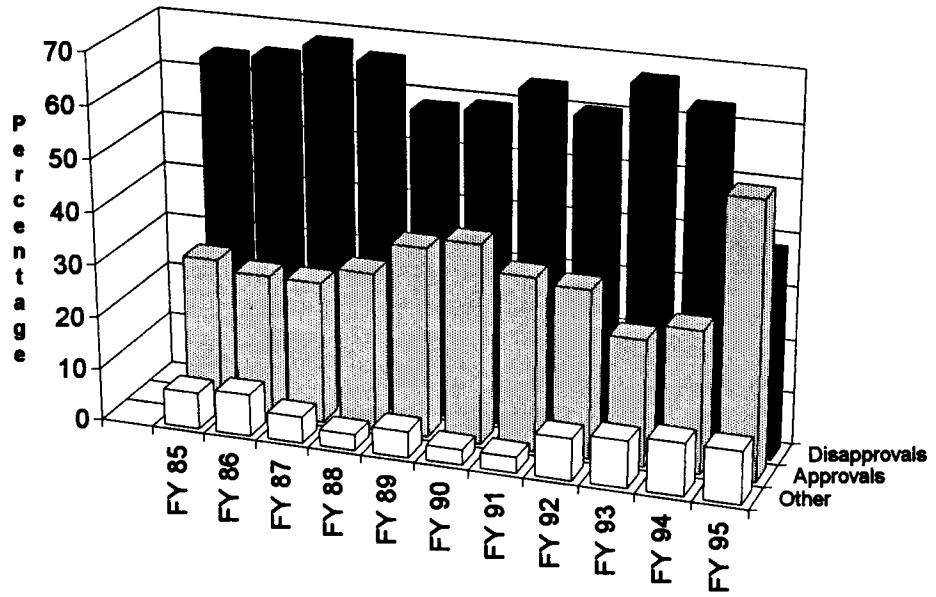


**Chart 13. Percentages of Types of Actions on Original IDE Decisions**




compared to 29 days last year. During FY 95, 92 percent of all original IDE decisions were issued within 30 days, down from 95 percent in FY 94. The decrease in this performance measure is due to ODE's move at the beginning of FY 95. During this period, 2 weeks was addeded to the due date on all original IDEs, amendments, and supplements.

Of the total decisions made on original IDEs in FY 95, the percentage of decisions that resulted in approval rose significantly from 30 percent in FY 94 to 57 percent in FY 95. This increase in the approval rate during the first review cycle is due in large part to the fact that the device industry and ODE have been working closely together during the pre-submission stage to improve the quality of the submissions and the interactive review. A high first round approval rate is important because it results in savings in cost and time for the FDA and industry alike.

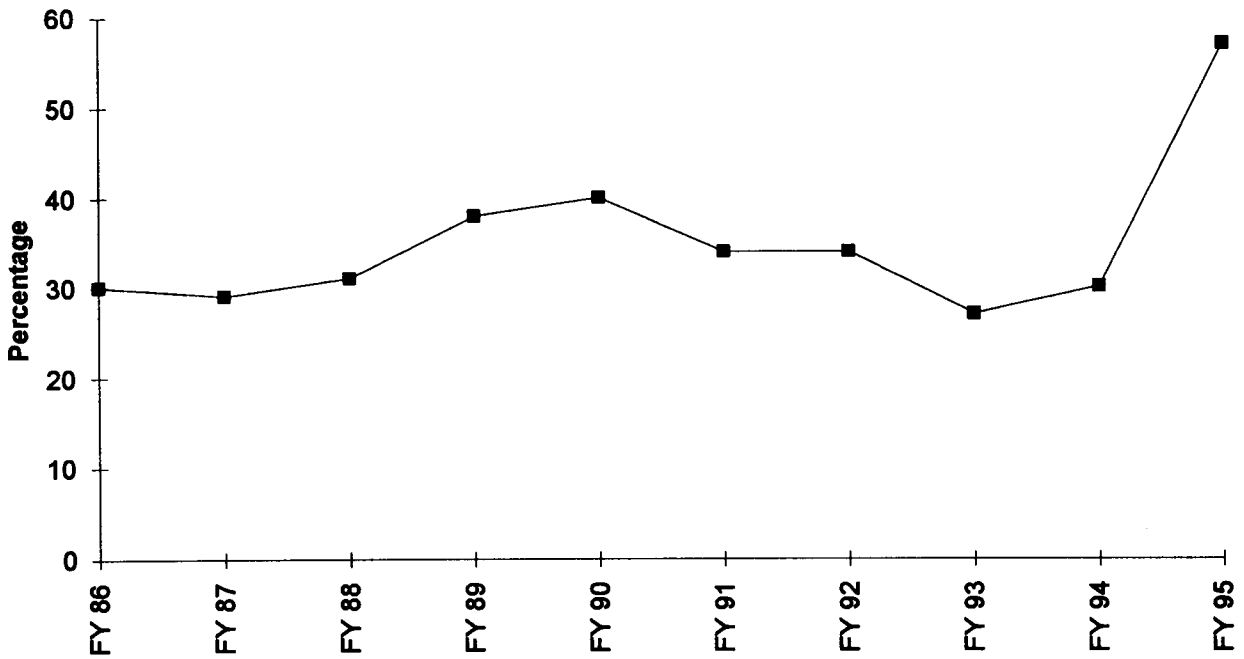
This year, for the first time, the annual report contains more detailed information concerning the number of original IDEs approved during the first review cycle. In the past, most IDEs were disapproved during the first review cycle, which necessitated the submission of one or more IDE amendments prior to approval. As stated above, these additional submissions are costly in time and manpower to both the FDA and the sponsor.

During FY 95, ODE made a concerted effort to increase the number of IDEs that were approved in the first 30 days and took several steps to accomplish this. ODE issued a new policy goal to

approve 66% of IDEs on the first review cycle. In support of this goal, review divisions have been issuing additional device specific guidance to help sponsors in the preparation of their study protocols and in determining the testing that is appropriate to the device and its use. In addition, review divisions and the IDE staff reviewed nearly 100 pre-IDE documents and conducted more than 200 presubmission meetings with IDE sponsors and this interactive review process provided specific guidance and clarifications prior to the submission of an IDE.

These efforts have paid-off handsomely. Of the IDEs which were complete enough to permit substantive review, the percentage of IDEs approved on the first review cycle increased from 30% in FY 94 to 57% during FY 95. Furthermore, during the first six months of FY 95 this percent-

**Chart 13A. Percentage of IDEs Approved on First Review Cycle***




* Based on those IDEs complete enough to permit substantive review.

age was 49% and increased to 65% during the second half of the fiscal year. This data is presented in Table 4., Part VI. Statistical Tables, and in a new Chart 13A.

2. IDE Amendments

Although not provided for in the IDE regulations, all submissions related to an original IDE that has been submitted, but not approved, are referred to as "IDE amendments". After an IDE is approved, related submissions are called "supplemental applications" under the regulations.

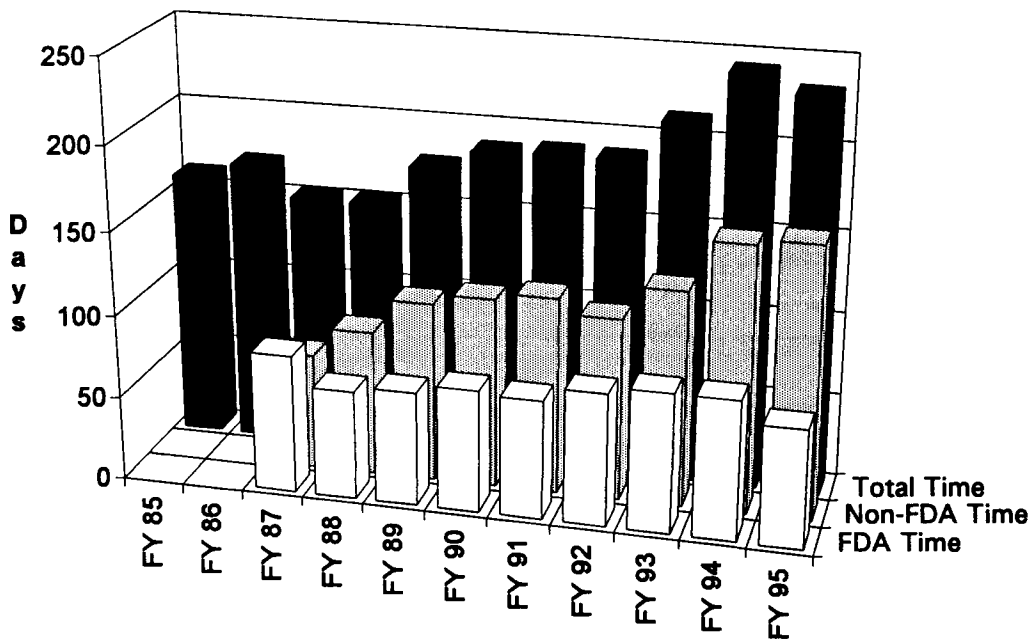
Identification of IDE amendments enables FDA to track each IDE from the time it is originally submitted until the time it is approved.

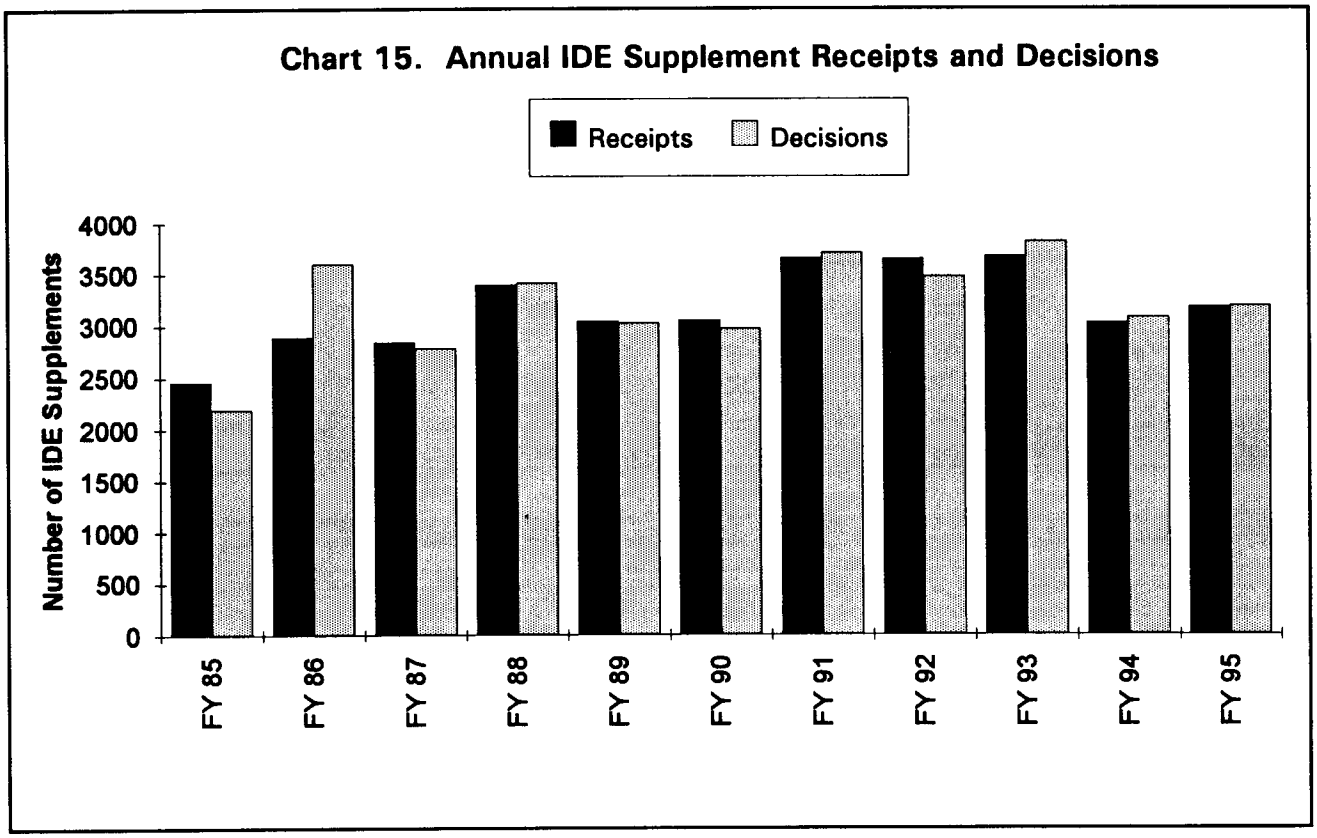
During this fiscal year, 210 amendments were received, down from 254 during the last fiscal year. Decisions were made on 213 amendments: 106 approvals (50%); 38 disapprovals (18%); and 69 other administrative actions (32%). Ninety-two percent of these decisions were made within 30 days. As was true for original IDEs, this percentage is down from FY 94 due to ODE's move in October 1995.

Each amendment is associated with an original IDE. Thus, approval of an amendment constitutes approval of the IDE, and the proposed investigation may begin. During FY 95, 106 approved amendments were related to 92 original IDEs, some of which were submitted to FDA prior to FY 95. There were 14 more amendments than original IDEs because some IDEs had more than one amendment.

As stated above, some of the 92 IDEs approved upon submission of an amendment during FY 95 were actually submitted in past years. A total of 166 amendments were submitted in support of these original IDE applications. This averages 1.8 amendments per IDE approved in FY 95.

**Chart 14. Average Approval Time for IDEs with Amendments**






It took an average total time of 232 days to approve IDEs in FY 95, down from 242 days in FY 94. This total approval time consisted of 70 days for FDA time, down from 83 days last year, and 162 days for non-FDA time, slightly up from 159 days in FY 94.

3. IDE Supplements

The IDE regulation requires the sponsor of an investigation of a significant risk device to submit a supplemental application for a number of reasons. For example, a sponsor must submit a supplement if there is a change in the investigational plan when such a change may affect the scientific soundness of the study or the rights, safety, or welfare of the subjects. Supplemental applications also are required for the addition of investigational sites. This regulation also requires the submission of various reports, which are logged in as supplements to IDE applications. These include reports on unanticipated adverse effects of the device; recall and device disposition; failure to obtain informed consent; and annual progress reports, final reports, investigator lists, and other reports requested by FDA.

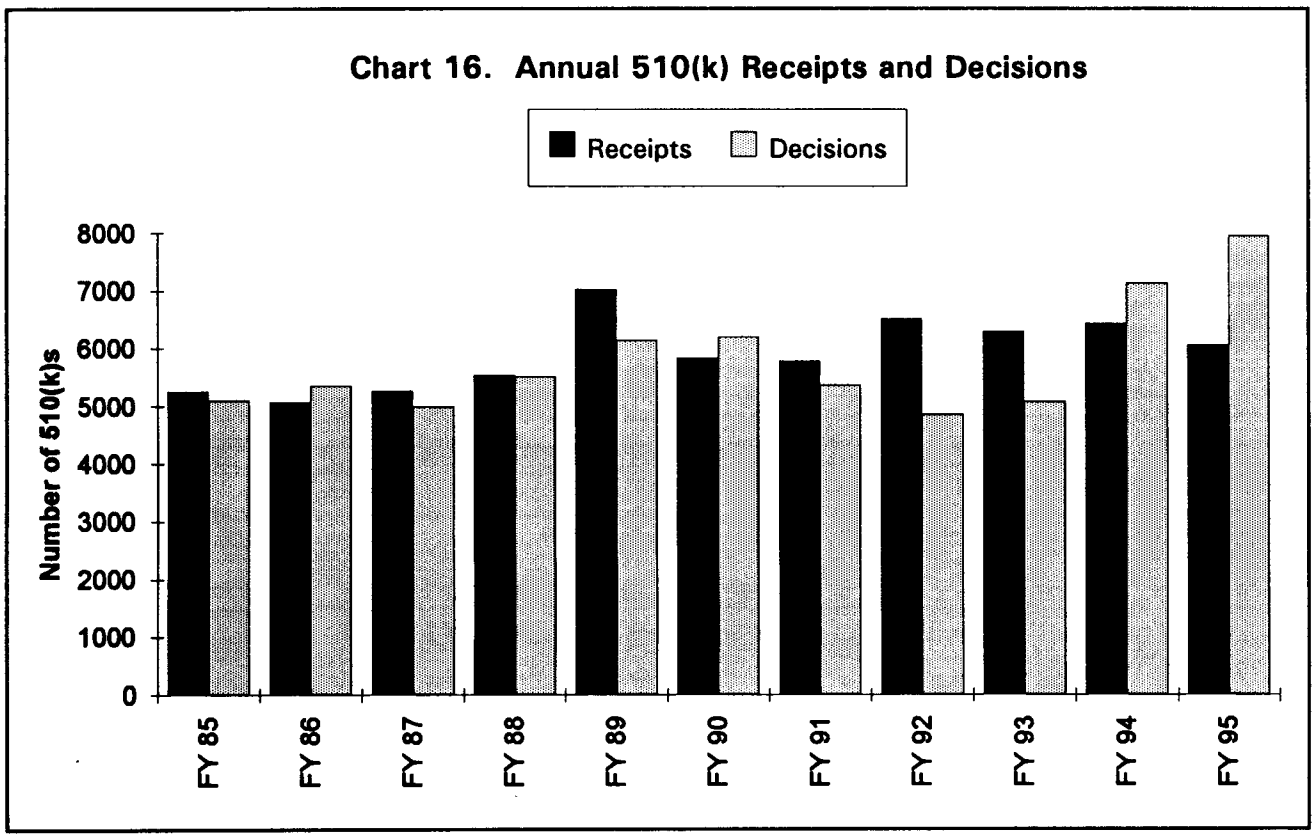
We received 3,171 IDE supplements during FY 95. There were no overdue supplements at the end of the year, and the percentage of supplements reviewed within the 30-day statutory timeframe remained at 98 percent in FY 95. The average review time for completing the review of IDE supplements dropped to 22 days.

## C. Premarket Notification (510(k))

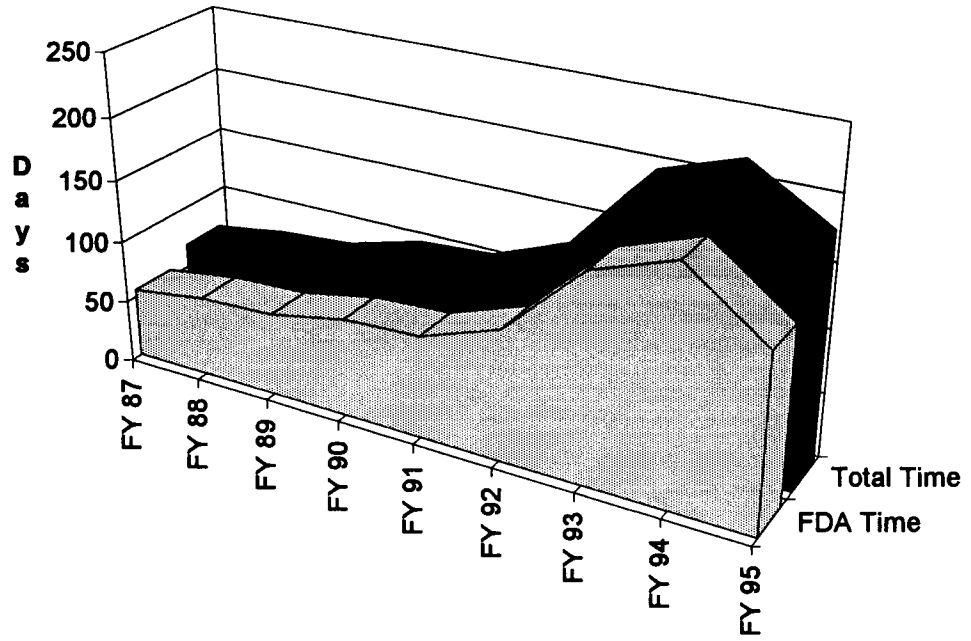
At least 90 days before placing a medical device into commercial distribution, a person required to register must submit to FDA a premarket notification, commonly known as a "510(k)". In addition to other information concerning the device, e.g., a description of the device, a 510(k) summary, or a 510(k)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

During this reporting period, ODE received 6,056 original 510(k)s and 4,552 510(k) supplements. A 510(k) supplement is a submission of additional information received in response to a request for additional information where the 510(k) had been placed on hold. Original and supplemental 510(k)s totaled 10,608 submissions, a decrease of 397 from the 11,005 received in FY 94. The 7,948 total decisions rendered on original 510(k)s during FY 95 is an increase of 813 over FY 94 and represents a new all-time record of 510(k) reviews completed in a single year.

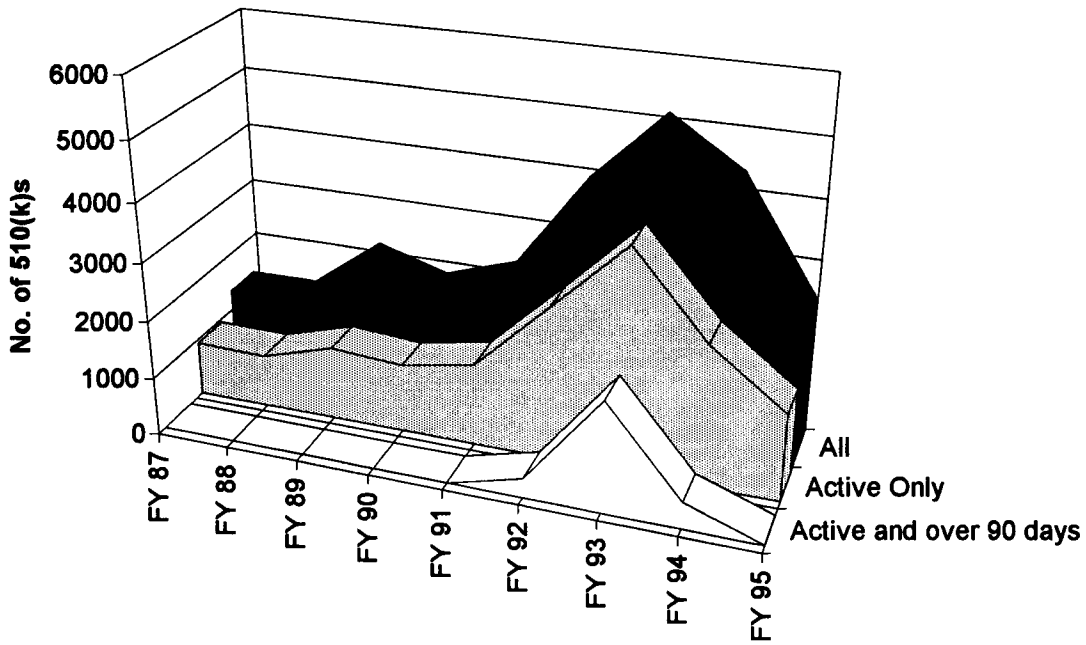
There are two average review times that traditionally have been reported for 510(k)s. The average review time based on total time is calculated, in part, by totaling all the time each 510(k) is being



## Chart 17. Average 510(k) Review Times




## Chart 18. Pending 510(k)s

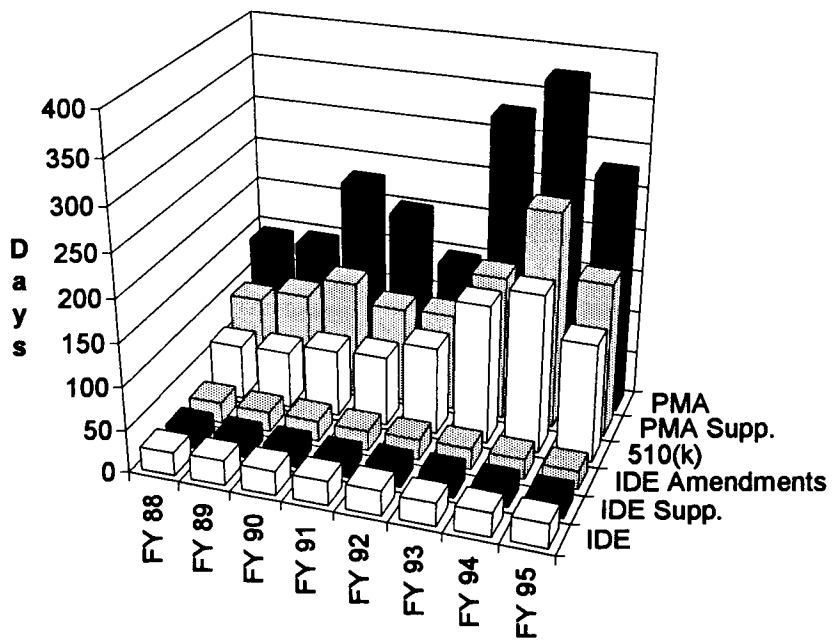


reviewed by FDA, plus all the time the 510(k) is on hold while it is under revision by the submitter. The FDA average review time is based only on the total of all of the times each 510(k) is reviewed by FDA. Both of these average review times decreased during FY 94, breaking a four-year trend in increasing 510(k) review times. The total average review time declined from 216 days in FY 94 to 178 days for FY 95 and the FDA review time decreased to 137 days from 184 days in FY 94.

The FY 95 Annual Report contains median review times for 510(k)s. These data appear in Table 7, Part VI. Statistical Tables. Based on FDA review time for FY 95, 50 percent of 510(k)s were completed in 91 days, compared to 134 days in FY 94. The 510(k)s in the 90th percentile were completed in 293 days. Based on total review time, which includes both FDA and non-FDA time, 50 percent of 510(k)s were completed in 102 days and the 510(k)s in the 90th percentile were completed in 428 days. This modal information should be more useful than average review times to manufacturers who wish to estimate how long it may take to get a final decision from the time a 510(k) is submitted.

There were 2,450 510(k)s in inventory at the end of this fiscal year, which is another significant decrease from the 4,374 510(k)s that were in FY 94's end-of-year inventory. The number on hold declined from 1,960 at the end of FY 94 to 964 at the end of this year. Most important, at the end of this reporting period only 9 510(k)s were active and overdue, as opposed to 1,894 in FY 93 and 460 in FY 94.

**Chart 19. Average FDA Review Times**



## D. Major Program and Policy Initiatives

During FY 95, ODE instituted a number of policy and program changes designed to improve the quality, efficiency, and timeliness of reviews and to improve compliance with the requirements in the PMA, IDE, and 510(k) programs.

### 1. FDA/HCFA Interagency Agreement Regarding Reimbursement for Certain Investigational Devices

On September 8, 1995, FDA entered into an interagency agreement with the Health Care Financing Administration (HCFA). The purpose of this cooperative effort was to facilitate reimbursement decisions by HCFA for investigational medical devices. According to the statute governing the Medicare program, HCFA is permitted to reimburse only for medical services and products deemed "reasonable and necessary" for the diagnosis or treatment of an illness or injury. The term "reasonable and necessary" has generally been interpreted to exclude coverage for experimental interventions; moreover, HCFA has historically viewed "investigational devices" (i.e., those not cleared or approved for marketing) as being experimental. There is increasing recognition, however, that many "investigational devices" are actually refinements of existing technologies or replications of technologies made by other manufacturers; and thus, such devices could be viewed as "reasonable and necessary" by Medicare.

Under the HCFA/FDA Interagency Agreement, FDA agreed to institute a procedure for providing certain information to HCFA to aid in its reimbursement decisions. The information supplied to HCFA will be used in determining whether to permit reimbursement under the Medicare program. Specifically, FDA agreed to categorize all FDA-approved IDEs as either "Experimental" or "Non-experimental/Investigational." "Non-experimental/Investigational" devices are those that are believed to be in Class I or II or devices believed to be in Class III for which the underlying questions of safety and effectiveness of the device type have been resolved, or it is known that the device type can be safe and effective, for example, because other manufacturers have obtained approval for that device type. According to a HCFA final rule, 60 *FR* 47982-98 (September 15, 1995), devices categorized as "Non-experimental/Investigational" would be eligible for Medicare coverage.

This initiative is expected to impact favorably on both patient care and the development of new medical technology. In addition, by expanding the Medicare coverage policy to include certain investigational devices, Medicare beneficiaries will be assured greater access to the latest medical advances.

This information is available to the public from the Division of Small Manufacturers Assistance (DSMA) on ELECTRONIC DOCKET (BBS) (800-252-1366 or 800-222-0185) and FACTS-ON-DEMAND (telefax) (800-899-0381).

2. New IDE Procedures and Performance Goals

In January 1995, ODE established two performance goals for the IDE Program and implemented several initiatives to facilitate the attainment of these goals. The first goal was to increase the approval rate for original IDE applications from the FY 94 rate of 30% to 66% by the end of the fiscal year. The second performance goal was to reduce the average number of review cycles from the past rate of 3.3 to less than 2.0. Brief summaries of the new strategies which were adopted by ODE in order to achieve these goals are:

· Pre-IDE Meetings: Sponsors are encouraged to meet with ODE staff before the IDE application is submitted for review. Such meetings should help familiarize the applicant with various FDA guidance documents, policies, and regulations and thus lead to more complete IDE submissions.

· Pre-IDE Applications: Prior to submitting a formal IDE application, sponsors are encouraged to submit preliminary information on those sections of the IDE for which they desire FDA guidance (e.g., clinical protocol design, pre-clinical testing, etc.). ODE staff would then be able to provide informal guidance to the industry before the official submission is made. Since this informal review would be conducted while other parts of the IDE are being prepared, it should not extend the total preparation time for the formal IDE application.

· Interactive Review Process: ODE reviewers are being urged to communicate frequently with the regulated industry during the review process in order to clarify ambiguities or remedy deficient information prior to completing the review. Such a process should help to reduce the number of review cycles to approval of the IDE application.

· New Strategies in the Clinical Development of Devices: In instances where the IDE application does not support the initiation of a large-scale investigation, ODE reviewers may advise sponsors to consider conducting a feasibility/pilot study. The conduct of a smaller trial would help address specific safety concerns; permit initial assessment of device design; and help define clinical endpoints, success/failure criteria, intended patient population, and the appropriate follow-up period before the multi-centered trial is initiated. The use of this type of trial not only permits initiation of an investigation which would have otherwise been disapproved but also provides for a better designed substantive trial for the marketing application.

As a result of these initiatives, ODE achieved an approval rate of 57% for original IDEs during FY 95 (65% for the second half of FY 95), and the average number of review cycles to approval was reduced to 2.8. In addition, ODE conducted more than 200 pre-IDE meetings and reviewed more than 100 pre-IDE submissions during the fiscal year.

3. Continued Access to Investigational Devices

In a May 10, 1995 memorandum to all ODE Review Staff, the Director of the Office reaffirmed ODE's policy regarding continued availability of investigational devices during the intervening period between completion of the clinical study and approval of the marketing application. Under this policy, IDE sponsors are permitted to continue to enroll subjects at a pre-determined rate while a marketing application is being prepared by the sponsor or reviewed by ODE if there is: (i) a public health need for the device, or (ii) preliminary evidence that the device is likely to be effective and no significant safety concerns have been identified for the proposed indication. Once a preliminary review of the data (IDE, 510(k), or PMA) indicates that there is evidence of safety and effectiveness, a sponsor may propose to conduct such an "extended" clinical investigation of the device via submission of an IDE supplement. The extended investigation may be conducted, for example, to obtain confirmatory evidence of safety and effectiveness in a subpopulation, to support new indications for use, to identify and quantify adverse reactions, to address long-term effects of the device, to support additional labeling claims, or to confirm that minor changes made to the device design do not substantially impact safety and effectiveness. This important policy allows the collection of additional safety and effectiveness data in support of the marketing application, permits new questions regarding the investigational device to be addressed during this intervening period, and allows uninterrupted access to potentially safe and effective devices.

4. Third-Party Review of Selected Premarket Notifications

The FDA held a public workshop on June 19, 1995 to discuss a proposed pilot program for third-party review of selected premarket notifications (510(k)s). The purpose of the workshop was to provide information on the pilot program and to obtain public comments and suggestions that might help FDA refine its plans for the pilot program. The pilot is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review as well as the promotion and protection of the public health. The pilot will be restricted to third-party review, but not clearance of 510(k)s. During the pilot, the third party will make a recommendation to FDA. FDA will then make a decision based on the third party's documented review. The purpose of the pilot is to test the feasibility of third-party review, including the willingness of qualified third parties to participate and the quality and timeliness of third-party reviews. Participating by manufacturers will be voluntary, i.e. manufacturers that do not want to participate may continue to submit 510(k)s directly to FDA. FDA intends to conduct the pilot for a 2-year period beginning early in fiscal year 1996. FDA is currently reviewing the comments received at the public workshop as well as written comments and FDA is preparing a *Federal Register* Notice announcing the initiation of the pilot.

5. 510(k) Exemptions

The policy of assigning devices to tiers (Triage) is an ongoing effort to allocate the Center's resources in the most efficient way to advance FDA's public health mission. Devices, regardless of their regulatory class, were assigned to Tier 1 if only a labeling review, primarily for intended use/indication for use, was necessary to provide a reasonable assurance of safety and effectiveness, and the devices posed a low or no risk to public health.
FDA is in the process of exempting devices assigned to Tier 1 from 510(k) premarket notification procedures. FDA has determined that manufacturers' submissions of premarket notifications for the devices proposed for exemption are unnecessary for the protection of public health, and accordingly:

Published a final rule in the *Federal Register* on December 7, 1994, to exempt 148 devices from premarket notification. FDA deferred action on 16 devices included in the proposed rule published in the *Federal Register* on July 21, 1994, to exempt 164 class I Tier 1 devices in order to resolve issues raised by comments received.

Published a final rule in the *Federal Register* on July 28, 1995, exempting 9 more devices, included in the proposed rule published in the *Federal Register* on July 28, 1994, from premarket notification.

Published a proposed rule in the *Federal Register* on July 28, 1995, to exempt 12 more class I Tier 1 devices from premarket notification and to reclassify into class I and exempt from premarket notification 112 class II Tier 1 devices.

As of January 6, 1995, 441 of the approximately 1,700 device types were exempted from premarket notification requirements. If the remaining proposals are finalized, 574 device types (74% of all class I devices and 33% of all classified devices) will be exempt from premarket notification.

6. Draft Guidance on 510(k)s for Device Modification

On August 1, 1995, the Center released a second draft guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." The availability of this draft for public comment was announced in the *Federal Register* on October 16, 1995. This second draft was responsive to the comments received on a previous draft that was also made available for public comment.

7. 510(k) Requirements

On December 14, 1994, FDA published the final rule on 510(k) Summaries, 510(k) Statements, Class III Summaries and Certifications, and revision of the regulation on confidentiality of infor-

mation on the existence of 510(k) submissions. This action is a continuation of efforts to implement provisions of the Safe Medical Devices Act of 1990 (the SMDA). The regulation, effective on March 14, 1995, lists the form and content required in the above. While a 510(k) Summary and 510(k) Statement have been required since April 1991 and a Class III Summary and Certification have been required since December 1990, the form and content are finalized by this final rule. The regulations on confidentiality of 510(k)s, regarding their existence, were revised to comply with the provisions of the SMDA. A new requirement, that all submitters certify to the truthfulness and accuracy of their submission, was included in the final rule at the request of the Office of the Inspector General, Health and Human Services.

8. International Harmonization of Guidance and Approach, ISO Toxicology Guidance

To harmonize its biological response testing with the requirements of other countries, FDA issued on May 1, 1995, a new blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." FDA will use the ISO standard, Part 1, instead of Tripartite Biocompatibility Guidance dated April 24, 1987.

ISO standard Part 1 includes two tables and provides guidance to select biological tests depending on the nature and duration of tissue contact.

The ISO standard acknowledges the difficulty in setting a single standard for all medical devices and states "due to diversity of medical devices, it is recognized that not all tests identified in a category will be necessary and practical for any given device. It is indispensable for testing that each device be considered on its own merits: additional tests not indicated in the table may be necessary."

In keeping with this inherent flexibility of the ISO standard, FDA has made a few modifications to the testing required by ISO standard to meet its regulatory mandate.

The ISO standard does not address the material mediated pyrogenicity and testing of devices which contact tissues such as nervous tissue and device materials which may have potential to cause immunological effects. FDA has routinely required this type of testing and the new blue book memorandum gives guidance on when these tests are required.

The new blue book guidance addresses the requirements for devices which are made of materials that have been well characterized chemically and physically and have a long history of safe use. For the purpose of demonstrating the substantial equivalence of such devices to other marketed products, it may not be necessary to conduct all the tests suggested in the FDA modified table. Therefore, ODE has developed a flow chart to help the ODE reviewers as well as the device manufacturers on the selection of toxicity tests and for determination when biocompatibility requirements are met for a particular device.

## E. Significant Medical Device Breakthroughs

On October 5, 1994, the Sonic Accelerated Fracture Healing System (SAFHS(R)) by Exogen, Inc., P900009, was approved. This is the first ultrasound device approved for the acceleration of the time to a healed fracture for fresh (i.e., within 7 days of the fracture), closed, posteriorly displaced, distal radius (Colles') fractures and fresh (i.e., within 7 days of the fracture), closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization.

On October 28, 1994, the EP Technologies, Inc.'s Cardiac Ablation System, P920047, the first radiofrequency powered catheter ablation system was approved. It is indicated for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia. The Medtronic CardioRhythm Atakr Ablation System, P930029, was approved February 9, 1995. Both submissions received expedited review.

On November 4, 1994, Chiron Vision Corporation's AdatoSil™ 5000 Silicone Oil, P910071, was approved as a first-of-a-kind under expedited review for reattaching the retina in certain complicated cases of retinal detachment. This device is an effective treatment for retinal detachment related to cytomegalovirus retinitis, which affects many AIDS patients.

On March 10, 1995, the OmniMed/ExciMed™ Laser System, P910067, from Summit Technology, Inc., was approved as a first-of-a-kind laser system for phototherapeutic keratectomy (PTK). This excimer laser was the first laser indicated for use in smoothing the corneal surface, and improving the topography and transparency of the cornea of patients with certain pathologic superficial corneal conditions. The second PTK laser, VISX, Inc.'s Excimer Laser System, P910062, was approved on September 29, 1995.

On June 9, 1995, Polymer Technology's Simplicity, P950010, for Rigid Gas Permeable Contact Lens Multipurpose lens care solution was approved. While there are a few multipurpose care products approved for soft contact lenses, this was the first for rigid contact lenses.

On June 20, 1995, Guidant Corporation's VIGOR DR/VIGOR SR Rate-Adaptive Pacemaker System, P940031, was approved. The VIGOR DR Pacemaker System is the first dual-chamber pacemaker system which demonstrates clinical benefit of adaptive-rate pacing with the use of an artificial sensor to detect physical activity.

On September 29, 1995, Neopath Inc.'s AutoPap 300 QC Automatic Pap Screener, P950009, was approved for marketing. This is the first automated cervical cytology screening device intended for use in the quality control and rescreening of previously screened negative Papanicolaou (Pap) smear slides.

On September 29, 1995, Datascope Corporation's VasoSeal Vascular Hemostasis Device (VHD), P920004, was approved. This device is the first of its kind and is intended to facilitate hemostasis and

decrease manual compression time after arterial puncture in patients who have undergone diagnostic angiography or percutaneous transluminal coronary angioplasty. This is accomplished by delivery of collagen into the tissue tract created by removal of a sheath device. The collagen interacts with platelets in order to create a hemostatic seal directly over the puncture wound in the artery.
On September 29, 1995, Schneider (USA) Inc.'s Wallstent TIPS (Transjugular Intrahepatic Portosystemic Shunt) Endoprosthesis, P930031, was approved under our expedited review program. This is the first approved use of a stent for the liver and is indicated for creation of intrahepatic shunt connections between the portal venous system and the hepatic vein for prophylaxis of variceal bleeding in the treatment of portal hypertension and its complications in patients who have previously failed conventional treatment techniques.

## F. Important Devices Cleared Via 510(k)

On March 21, 1995, the first latex allergen for use as an in-vitro diagnostic allergen-specific test was cleared via 510(k). Diagnostic Products Corp.'s, K931746, AlaSTAT Allergen-Specific IgE system is used to measure circulating levels of IgE specific to latex to aid in the clinical diagnosis of IgE mediated allergic disorders. Anaphylactic allergic reactions to materials containing latex have resulted in concern regarding the need to identify latex sensitive individuals.

On April 3, 1995, the ThermoLase Corporation's Nd:YAG laser, K950019, for hair removal when used with a proprietary solution was cleared. This decision was based on clinical data and the laser itself is similar in specifications with other Nd:YAG lasers presently cleared for other dermatological uses such as tattoo removal and treatment of vascular lesions. This clearance continues to produce phone inquiries from consumers interested in this application and from electrologists' associations. This device is the first laser electrolysis.

On April 28, 1995, River Medical's SmartDose™ Prefilled Infusion System, K943692, was cleared for marketing. The SmartDose™ is a single use disposable infusion pump prefilled with a diluent, either 0.9% NaCl Injection, USP or 5% Dextrose Injection, USP. This drug/device combination product was designated as a device under the InterCenter Agreement and through the Request for Designation process; the Center for Drug Evaluation and Research provided a consultant review of the diluents. This product represents the first diluent prefilled pump to be cleared by the Agency.

On May 8, 1995, Ostex International Inc.'s Osteomark urine test, K945946, was cleared for marketing. This device will allow doctors to show osteoporosis patients whether medications are slowing their bone loss. Osteoporosis afflicts 25 million Americans.

On May 15, 1995, T Cell Diagnostic's, TRAx CD4 ELISA Test Kit, K925255, intended for the quantitative measurement of total CD4 protein in whole blood was cleared for marketing. The predicate device is the flow cytometric measurement of CD4 positive lymphocytes in whole blood and the monocytes are excluded from the analysis gates; only intact lymphocytes are analyzed so that the soluble CD4 in the plasma does not contribute to the total count.

On July 13, 1995, Dade International's Stratus Cardiac Troponin-I Fluorometric Immunoassay and Calibrators, K951890 and K951888, were cleared as a new analyte for use in the diagnosis of acute myocardial infarction (AMI). Based on cumulative data, Troponin-I appears in the blood as early as 4-8 hours after the onset of chest pain, levels peak at 12-16 hours, and then remain elevated as long as 5-9 days. This temporal pattern suggests that this marker could be useful as an adjunctive laboratory test to traditional diagnostic methods such as ECG and patient history.

On July 14, 1995, Sudormed, Inc.'s Sweat Collection Patch and SolarCare Technology's EIA Microplate Assays for Cocaine, K926253 and K934775, Amphetamines, K935588 and K935573 and Opiates, K935564 and K935565 were cleared for marketing. The patch and assay system intended for use with sweat offer an advantageous alternative over the traditional urine testing. There is less inconvenience, and urine testing for drugs is only generally effective if the urine collection is within 36 hours of drug ingestion while sweat collection for drugs permits continous monitoring of a subject's drug use for up to a period of 7 days..

On September 8, 1995, Target Therapeutics' Guglielmi Detachable Coil, K951256, was cleared for marketing. This device is the first of its kind and is intended for embolization of saccular intracranial aneurysms that, because of their morphology, location, or patient's general medical condition are considered by the treating neurosurgical team to be inoperable or to be very high risk for management by traditional operative techniques.

On September 15, 1995, Base Ten, Inc.'s PRENVAL, K953652, a computer software device to aid in database management, calculation of the multiple of the median, and generation of reports from quantitative AFP measurements was cleared for marketing.

On September 21, 1995, Adeza Biomedical Corporation's Fetal Fibronectin Enzyme Immunoassay Kit, P920048, was approved under our expedited review program. This device is a first-of-a-kind as an aid in assessing the risk of preterm delivery in $\geq$7 days or $\geq$14 days from the time of sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes and minimal cervical dilatation (<3 cm), sampled between 24 weeks, 0 days and 34 weeks, 6 days gestation. The device represents a clinically meaningful advantage over conventional diagnostic methods used to identify symptomatic women at risk for preterm delivery.

On September 25, 1995, Meco Industries' Meconium Drug Testing Kit, K945207, was cleared. The device is a meconium processor and RIA method intended for use in preparing meconium into suitable form for analysis of drugs of abuse (cocaine, opiate, and cannabinoid). This test provides a preliminary result that is useful in establishing in-utero drug exposure to the infant to allow appropriate withdrawal treatment; especially when the mother is suspected of drug abuse.

## G. Goals for FY 96

In light of our present resources and workload, the ODE staff will strive to increase efficiency and scientific rigor in the following areas:

### 1. 510(k)s

Our goal is to screen for completeness within 30 days and perform at least one cycle of in-depth review on all submissions within a 90-day review cycle. We will also maintain the average review time at less than 90 days per cycle which should prevent the accumulation of a new 510(k) backlog.

### 2. PMAs

Our goal is to finish at least one full cycle of complete review for all new applications identified for expedited review and communicate the written results of our review to the applicant within 180 days of submission. For expedited applications with major deficiencies, our goal is to complete a second review cycle within 90 days of receiving complete answers to the deficiencies. For other new PMAs, our goal is to have at least 75 percent of first-cycle reviews completed and action taken within a year after filing. We want to continue to emphasize timely completion of post-advisory panel PMAs and take post-panel action (nonapproval, approvable, additional information letter or approval) on these PMAs within 30 days of the panel meetings.

### 3. IDEs

Our goal is to improve the gains of this year by continuing to encourage early meetings with firms sponsoring research on new devices. This effort should assist them in getting approval earlier in the IDE process. First round approval rates are expected to increase due to this effort.

### 4. Consistency in Applying Regulations

Our goal is to strengthen consistency of decision-making within product lines. Managers and division directors will continue to be empowered with greater decision-making authority. Furthermore, we will continue to strengthen the guidance available to our reviewers and the industry, as well as improve mechanisms to enhance communication among our division directors. This will help ensure that we are working from the same set of assumptions and guiding principles as we make product approval decisions.

## 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

Over the years manufacturers have requested more information on the factors that were material to the review of submissions for specific medical devices. In response to these requests, ODE review divisions have issued an increasing number of guidance documents that set forth the considerations that go into the review of submissions for specific devices.

In general, "guidance documents" are statements of advice or opinions to the regulated industry, which do not have to be announced in the *Federal Register*. A guidance document is informal advice from FDA and is not binding on the regulated industry or the agency. It "does not bind FDA and it does not create or confer any rights, privileges, or benefits for or on any persons." Accordingly, ODE reviewers do not cite the failure to comply with a guidance document in deficiency letters or letters requesting additional information.

Within ODE, guidance documents are designed to promote uniformity and to improve the efficiency, administration, and quality of ODE programs. At the division level, a "device-specific" guidance document is issued by the division that has review jurisdiction over the type of device that is the subject of the guidance. Depending upon the need, guidance documents have covered a variety of topics, such as device testing, clinical trials, labeling, indications for use, etc. Not every guidance covers all of the same topics. Guidance documents have been developed for PMAs, 510(k)s, and IDEs.

Guidance documents undergo various levels of review and public comment. Some simple guidance documents are prepared in-house and issued without public review and comment. More complex guidance documents that deal with matters of wide public interest are the subject of discussion and comment at public advisory committee meetings and professional and scientific meetings, and often receive comments from industry trade groups and other members of the public. Guidance documents are revised as circumstances warrant.

During FY 95, ODE and its review divisions issued 51 guidance documents. These guidance documents are listed and described in Appendix A.

In addition to dissemination of these guidance documents to appropriate ODE staff members, they are widely distributed to the affected industry through trade associations, the trade press, and directly to firms, and they are available to interested members of the public. All ODE guidance documents are available from the Division of Small Manufacturers Assistance (DSMA) (HFZ-220) on the Center's Electronic Docket, a computer-based bulletin board system, via telefax and in hard copy at: ELECTRONIC DOCKET (BBS): (800) 252-1366 or (301) 594-2741; FACTS-ON-DEMAND (telefax):

(800) 899-0381 or (301) 827-0111; MAIL: 1350 Piccard Drive, Rockville, Maryland 20850-4307; or, VOICE: (800) 638-2041 or (301) 443-6597.

## B. Reclassification/Classification of Devices

### 1. Reclassification of Classified Devices

The FDA has continued to implement the Preamendments Class III Devices Strategy Document (notice of availability in the *Federal Register*, May 6, 1994). The strategy document sets forth the agency's strategy for implementing Section 515(i) of the Food, Drug, and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, which requires FDA to review the classification of preamendments class III (premarket approval) devices and either reclassify the devices into class I (general controls) or class II (special controls) or retain them in class III.

The strategy document, which is currently being implemented, identifies three groups of preamendments class III devices. Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness but are no longer used, or in very limited use. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. Group 3 devices, which include 15 high-priority devices, are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification.

*Final Reclassification Actions:*

Published a final rule in the *Federal Register* on December 7, 1994, exempting 148 class I devices from premarket notification.

Issued a reclassification order on May 19, 1995 to reclassify surgeon's instruments used with cochlear implants from class III to class I.

Published a final rule in the *Federal Register* on July 27, 1995, revoking the exemption of Blood Culture System Devices from premarket notification.

Published a final rule in the *Federal Register* on July 28, 1995, exempting 9 class I devices from premarket notification.

Published a withdrawal in the *Federal Register* on July 28, 1995, of a proposal (published in *Federal Register* on July 21, 1994) to exempt 7 class I devices from premarket notification.

*Proposed Reclassification Actions:*

Published a proposed rule in the *Federal Register* on July 28, 1995, to reclassify 112 devices from class II to class I and to exempt those 112 reclassified devices and 12 additional class I devices from premarket notification.

*Recommended Reclassification Actions:*

On October 21, 1994, the Hematology and Pathology Devices Panel recommended the reclassification/classification of immunohistochemical stains from class III to class II (preamendment status determination pending).

On August 21, 1995 the Cardiovascular Devices Panel recommended the reclassification of the non-roller type cardiopulmonary bypass pump from class III to class II.

2. Classification of Unclassified Devices

*Final Classification Actions:*

Published a final rule in the *Federal Register* on December 20, 1994 to classify Temporomandibular Joint Prostheses in class III.

Published a final rule in the *Federal Register* on December 30, 1994 to classify Glans Condoms in class III.

Published a final rule in the *Federal Register* on July 18, 1995 to classify Transilluminators for Breast Evaluation in class III.

*Proposed Classification Actions:*

Published a proposed rule in the *Federal Register* on January 13, 1995 to classify Transilluminators for Breast Evaluation in class III.

*Recommended Classification Actions:*

On January 26, 1995, the Ophthalmic Devices Advisory Panel recommended the classification of contact lens cases and endoilluminators in class II.

On July 17 and 18, 1995, the General Hospital Devices Advisory Panel recommended the classification of apgar timers, lice removal kits and infusion stands in class I, exempt from premarket notification and Good Manufacturing Practices; general purpose disinfectants in class I, exempt from premarket notification; and sterilants into class II.

On July 21, 1995, the Ophthalmic Devices Advisory Panel recommended the classification of non-strabismic visual trainers in class I and strabismic trainers in class II.

On August 8, 1995, the Dental Products Advisory Panel completed their recommendations for classification of bone filling and bone augmentation devices into class II and class III.

3. Other Implementation of Strategy (515(i) Regulations)

Published a notice in the *Federal Register* on August 14, 1995 requesting the submission of safety and effectiveness information for Group 2 preamendments class III devices.

Published a notice in the *Federal Register* on August 14, 1995 requesting the submission of safety and effectiveness information for Group 3 low- and medium-priority preamendments class III devices.

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

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

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

*Final 515(b) Actions:*

Published a notice in the *Federal Register* on October 14, 1994, to rescind the notice of applicability of 515(b) procedures to replacement heart valve allografts.

Published a 515(b) final Rule in the *Federal Register* on April 5, 1995, for the testicular prosthesis device.

Published a (515(b) final rule in the *Federal Register* on August 24, 1995, for cranial electrotherapy stimulator devices.

*Proposed 515(b) Actions:*

Published a 515(b) proposed rule; opportunity to request reclassification in the *Federal Register* on February 15, 1995, for the mechanical/hydraulic urinary incontinence device.

Published a 515(b) proposed rule; opportunity to request reclassification in the *Federal Register* on June 7, 1995, for the endodontic heat sterilizer device.

Published a 515(b) proposed rule; opportunity to request reclassification in the *Federal Register* on July 11, 1995, for OTC denture cushions or pads and OTC denture repair kits.

Published a 515(b) proposed rule; opportunity to request reclassification in the *Federal Register* on September 7, 1995, for class III pre-amendments Group 1 devices.

## D. Standards Activities

The definition of Class II devices in Section 513(a)(1)(B) was modified by the Safe Medical Devices Act (SMDA) (21 U.S.C. 360c) to include devices for which there is sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, and other appropriate actions. In addition, Section 514 which defines the procedures for promulgation of performance standards, the only control available for class II devices prior to SMDA, has been revised to facilitate the process. Performance standards are valuable regulatory tools for some devices. Since the enactment of SMDA, two performance standards have been proposed as follows:

1. Regulatory Standards

FDA published a proposed rule in the *Federal Register* on February 21, 1995, to establish a mandatory performance standard for infant apnea monitors, also called neonatal apnea monitors.

FDA published a proposed rule in the *Federal Register* on June 21, 1995, to establish a mandatory performance standard for electrode lead wires and to make unprotected electrode lead wires a banned device upon the effective date of the standard.

2. Consensus Standards

About 90 ODE staff members participated in more than 200 standards development activities during FY 95. It is intended that these activities will result in standards that can be used during device review.

Currently, more than 300 direct references to consensus standards are contained in device reviewer guidance documents.

## E. Advisory Panel Activities

The Medical Devices Advisory Committee provides advice to FDA on the safety and effectiveness of marketed and investigational devices, the classification of devices into one of three regulatory categories, the possible risks to health associated with the use of devices, the formulation of product devel-

opment protocols, the review of premarket approval applications, and the content of guidelines or guidance documents designed to improve the interaction between the Agency and sponsors of medical devices. The Committee is divided into 16 panels according to medical device specialty.

ODE held 28 panel meetings during FY 95 involving 40 meeting days. Each panel met at least once (three panels met three times). There were 13 formal training sessions held for new panel members. Several Executive Secretaries have rotated out of the position and new staff have been identified for this leadership position.

The Agency received valuable advice on a variety of medical devices such as tumor markers, excimer lasers, implantable defibrillators, lasers used in general surgery and extracorporeal removal of low density lipoprotein (LDL) to lower LDL cholesterol in patients with familial hypercholesterolemia.

1. Diversity of Panel Membership

Members are leading authorities in a broad range of medical specialties and have current experience in medical practice, teaching and/or research. Each panel has at least one consumer and one industry representative. Qualified female and minority representation is encouraged; currently females make up over a third of our membership and minorities almost 24%.

2. Training for Executive Secretaries

ODE Executive Secretaries attended an Agency training session on the recently developed Consultants File database. Each Executive Secretary is responsible for entering information about each member of their committee/panel into the database which can be shared by all Executive Secretaries.

The ODE Advisory Panel Coordinator held monthly meetings to discuss a variety of timely issues (i.e. amendment to the Medical Devices Advisory Committee Charter, panel member vacancies, committee management issues, voting options and parliamentary procedures, FOI considerations, classification and reclassification training, new financial disclosure form).

## F. ODE Integrity Program

1. Data Integrity

During FY 95, it was necessary to investigate integrity issues in more than 38 instances. Most cases necessitated data audits of premarketing submissions. Some of these integrity issues were based, in part, upon internal inconsistencies within the submission, scientifically implausible data, contradictory information provided by scientific/clinical researchers, data inconsistent with the

scientific/professional literature, information provided by employees of the applicant, and information obtained from legal documents.

This year saw the issuance of four letters to medical device firms by the Center for Devices and Radiological Health pursuant to FDA's "Application Integrity Program" (AIP); formerly known as the "Fraud Policy." Under the AIP, the substantive review of all pending firms to whom the AIP letters were issued is suspended until the firms undertake an internal audit and implement an acceptable corrective action plan.

On the other side of the coin, FDA removed AIP restrictions from one firm that had previously been sent an AIP letter. This firm had successfully implemented a corrective action plan and FDA now accepts and conducts substantive reviews of premarketing applications from the firm.

2. Program Integrity

During FY 95, more than 37 ethics issues and conflicts of interest problems arose. Several of these questions involved claims by manufacturers that they were not receiving fair or equal treatment during the review process. Other issues involved the receipt by ODE staff of free training, travel expenses, meals, cash honoraria, and other things of value from persons outside the government. Some questions involved the acceptance of faculty appointments and participation in committee activities of professional associations.

This fiscal year, ODE, in conjunction with the Office of Compliance, prepared and conducted two seminars for Center staff entitled "RS Medical: A Case Study - Lessons Learned." The purpose of this seminar was to explore the events leading up to major civil litigation in which FDA was found to be responsible for improper conduct in regulatory activities related to this firm.

## G. Responding to Congressional Inquiries

Congressional interest in ODE programs continued to be strong during this fiscal year. Over the past year, ODE staff responded to 39 Congressional letters. Most inquiries related to pedicle screws, immunohistochemical, breast implants, and muscle monitoring devices. In addition, the Subcommittee on Oversight and Investigation and the House Appropriations Committee held hearings and requested documentation and information relating to the implementation and enforcement of the Food, Drug and Cosmetic Act.

## H. Responding to FOI Requests

Under the Freedom of Information (FOI) Act, FDA must respond to requests for information contained within agency files, with the exception of trade secret data and confidential commercial infor-

mation. Requested documents must be "purged" of such privileged information before release. ODE staff received 1,378 FOI requests during FY 95 indicating a steady increase over the last three years (943 in FY 94, 976 in FY 93, and 1,052 in FY 92).

## I. Publications

During FY 95, the Office of Device Evaluation cleared 6 abstracts and 7 manuscripts authored by ODE staff for publication in professional and scientific journals, and 17 presentations delivered by ODE staff at professional and scientific and trade association meetings. See Appendix B for a bibliography of publications.

# V. SUPPORT ACTIVITIES

## A. Recruitment and Hiring Effort

In 1995, ODE continued an active recruitment program (responding to over 800 letters of inquiry) resulting in the hiring of 32 new employees (20 scientific reviewers, 7 medical officers, and 5 support personnel). Fifteen new hires (47%) were members of minority groups. During FY 95 ODE lost 28 employees (16 scientific reviewers, 6 medical officers, and 6 support personnel). One fourth of the losses can be attributed to the early-out incentive and retirement programs offered to government employees.

In an effort to obtain highly qualified scientists, engineers, medical officers, and other clinicians, recruitment packages, flyers, press clips, letters, and personal contacts were used to publicize the availability of jobs in ODE.

## B. Professional Development

Professional development at all employee levels continued to be a vital segment of ODE's support activities in FY 95. ODE developed FY 94 training initiatives for major on-going staff development and industry outreach programs. These programs included numerous in-house and off-site activities that took the form of workshops, seminars, informational exchange seminars, and structured courses at accredited educational institutions. Training for Center Advisory Panels is discussed in Section IV-E above.

### 1. Staff Training

ODE continued to extensively train all new staff in FY 95. New reviewers attended the ODE "New Reviewer Training" course conducted in conjunction with the CDRH Staff College. In addition, new reviewers participated in the "Mentor Program" within ODE which provided them the opportunity to work with experienced ODE employees to become more quickly assimilated into the organization.

In addition to providing training designed for new employees, ODE sponsored employee attendance at college courses at accredited universities and at numerous workshops and seminars on-site or in the Washington Metropolitan Area. Some specific in-house courses were: Underwriters Lab Seminar, Total Quality Management, The Employee Workshop for Organizational Change, Scientific and Technical Writing, Exceptional Customer Service, and The Grammar Game.

During FY 95, all ODE employees attended HIV/AIDS Training. This training was designed to orient federal government employees on how to treat the sensitive issues surrounding AIDS and HIV in the workplace.

2. Industry Outreach

The purpose of ODE's industry outreach programs is to enhance ODE reviewers' knowledge of and hands-on experience with devices in their distinctive device review areas.

*ODE Vendor Days*

In FY 95, ODE continued to sponsor informational exchange seminars with various device manufacturers. On December 9, 1994, ODE supported a "Vendor Day" with DNA amplification manufacturers. This 4-hour seminar included a presentation and demonstration of the various DNA amplification techniques. On May 23 and 24, 1995, ODE hosted a "Vendor Day" with pacemaker and implantable defibrillator manufacturers. This workshop, consisting of two 4-hour sessions, included presentations and demonstrations on pacemakers the first day and defibrillators on the second day.

*ODE Site Visits*

In FY 95, ODE formally activated its "Site Visit" program which was developed to enhance reviewer knowledge of how a specific regulated device is manufactured and tested. The FY 95 site visits included meeting with manufacturers in the areas of contact lenses and intraocular lenses, pacemakers and defibrillators, obstetrics/gynecology, gastroenterology/renal devices and urology and lithotripsy devices. These group "Site Visits" introduced an additional vehicle for reviewers to learn about a specific device by providing hands-on experience.

3. Information Exchange

ODE participated in informational exchange meetings and seminars sponsored by health care associations, academia, other government agencies, consumer groups, etc., and with other Offices within CDRH in FY 95, such as the CDRH Scientific Roundtables and OSB Safety Conferences. In addition to the exchange of information outside ODE, supervisors continued to participate in monthly meetings to discuss current management issues, and all employees attended in-house workshops to learn about current technologies and new policies and procedures.

## C. Office Automation

ODE continued to improve its base of equipment and its computer systems in FY 95 with the installation of 62 new 486 PCs, 10 new network printers, 2 laser printers for IMAGE, new software, software upgrades, computer memory and larger hard drives. Reviewer access to the IMAGE system (optical storage and retrieval) was improved by enabling use of employees' desktop PCs to view

documents stored on optical disk. Two remaining ODE tracking systems (the ODE Division Tracking System and the PMA Tracking System) were converted to Oracle. ODE continued to pilot electronic submissions in its effort to move toward the electronic review of device applications and ODE began sending 510(k) final decision letters by FAX to device sponsors to speed the transmission of ODE decisions. Overall, FY 95 proved to be a year of increased use of computer technology benefitting device sponsors and ODE reviewers as they worked together on review activities.

## 1. Tracking Systems

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

The major overhaul of the ODE Division Tracking System provides additional capabilities which were not available in the former system. It relies on user "roles" defining the level of access for reviewers, team leaders, branch chiefs, and division directors to ensure the integrity of the data. This new flexibility allows reviewers to track their own documents and use document information already entered at the division and branch levels. The system also allows the tracking of document types other than PMA, 510(k), and IDEs, such as consults from other FDA Centers, congressional inquiries, FOI requests, internal health hazard evaluations, and more. It allows the tracking of consulting and group reviews among divisions. Furthermore, enhanced reports and interactive displays, such as workload analysis and PMA timeline display, allow divisions to better manage their workload.

In addition to the major accomplishment of creating a new division tracking system, OIS completed another major initiative in converting the PMA Tracking System to Oracle in May. The new system uses many of the same searching and data entry techniques as the previously converted 510(k) and IDE Tracking Systems. Additionally, it addresses many of the problems associated with the PMA Timeline and clock starting/stopping which were inherent in the earlier system.

## 2. Document Imaging

ODE's use of IMAGE continued to grow during FY 95 as many reviewers obtained the IMAGE software on their PC to allow speedier IMAGE access from their desktop. Formerly, all reviewers had to share access to the IMAGE system from common IMAGE stations.

The number of documents available for viewing continues to increase each year as new documents are scanned. However, many older documents will never be available on IMAGE since the

hard copies are not available for scanning. Those documents will continue to be available for retrieval from microfiche. ODE continued scanning PMA originals, PMA amendments, and PMA supplements related to scanned originals on arrival. Device Master Files were also scanned on arrival.

3. Electronic Submission Pilot Projects

ODE continued to conduct pilot projects on the electronic submission of device applications by device sponsors utilizing an alternative software platform, Adobe Acrobat. This platform allows the device sponsor to create a document in any software and then save the document as a post-script text file which can be read with an Acrobat Reader or Exchange.

ODE will continue to pilot the processing of electronic submissions in FY 96. While many reviewers lack the necessary hardware to review electronic submissions, ODE plans to replace its 386 PCs with Pentium PCs to enable additional reviewers to accept and process applications electronically.

4. Video Conferencing

ODE received a Pentium PC with the Intel Proshare software to allow reviewers to communicate with device sponsors. ODE can link to other PCs running the Proshare software to collaborate on a document, share software applications, and send and receive files. In the future, Proshare will be able to do document sharing and exchange files with other video conferencing software.

5. Faxing 510(k) Decision Letters

On May 15, 1995, ODE began faxing 510(k) decision letters to 510(k) holders after the 510(k) decision letter was dated and mailed to the 510(k) holder. This effort was initiated to provide a quick response by eliminating mail delays. Letters are sent by fax to 510(k) holder if the fax number was provided in the 510(k) submission.

## D. Facilities and Equipment

In October 1995, ODE moved to new quarters at 9200 Corporate Boulevard, Rockville, Maryland 20850. This move, which included all divisions except DCLD, was executed over the course of two separate weekends with a minimum of disruption to the review process. DCLD moved to 2098 Gaither Road, Rockville, Maryland 20850, during the summer of 1994.

## VI. STATISTICAL TABLES

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

**Table 1. PMA/IDE/510(k) Submissions Received**
**FY 91 - FY 95**

| Type of Submission | No. Received | | | | |
|---|---|---|---|---|---|
| | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
| Premarket Approval (PMAs) | | | | | |
| Original Applications | 75 | 65 | 40 | 43 | 39 |
| Amendments | 680 | 740 | 665 | 704 | 812 |
| Supplements | 593 | 606 | 395 | 372 | 499 |
| Amendments to Supplements | 954 | 897 | 782 | 788 | 838 |
| Reports for Orig. Applications | 441 | 483 | 442 | 407 | 487 |
| Reports for Supplements | 15 | 21 | 17 | 12 | 8 |
| Master Files | 42 | 41 | 71 | 130 | 92 |
| PMA Subtotal | 2,800 | 2,853 | 2,412 | 2,456 | 2,775 |
| Investigational Device Exemptions (IDEs) | | | | | |
| Original Appplications | 213 | 229 | 241 | 171 | 214 |
| Amendments | 283 | 297 | 320 | 254 | 210 |
| Supplements | 3,647 | 3,644 | 3,668 | 3,020 | 3,171 |
| IDE Subtotal | 4,143 | 4,170 | 4,229 | 3,445 | 3,595 |
| Premarket Notification (510(k)s) | | | | | |
| Original Notifications | 5,770 | 6,509 | 6,288 | 6,434 | 6,056 |
| Supplements | 3,752 | 4,555 | 3,940 | 4,571 | 4,552 |
| 510(k) Subtotal | 9,687 | 11,064 | 10,228 | 11,005 | 10,608 |
| PMA/IDE/510(k) Total | 16,639 | 18,086 | 16,869 | 16,905 | 16,978 |

**Table 2. Original PMAs**
**FY 91 - FY 95**

| Action | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
|---|---|---|---|---|---|
| Number Received | 75 | 65 | 40 | 43 | 39 |
| PMA Actions | | | | | |
| Filing Decisions | | | | | |
| Filed (%) | 52(50) | 46(54) | 33(62) | 38(60) | 33(60) |
| Not Filed (%) | 42(40) | 28(33) | 16(30) | 25(40) | 22(40) |
| Others(%) | 10(10) | 11(13) | 4 (8) | 0( 0) | 0( 0) |
| Filing Decision Subtotal | 104 | 85 | 53 | 63 | 55 |
| Review Activities | | | | | |
| Major Deficiencies | 28 | 31 | 21 | 30 | 29 |
| Minor Deficiencies | 5 | 5 | 10 | 4 | 7 |
| Other[a] | 127 | 162 | 171 | 191 | 111 |
| Review Activity Subtotal | 160 | 198 | 202 | 225 | 147 |
| Approval Decisions | | | | | |
| Approvals(%) | 27(27) | 12(24) | 24(35) | 26(39) | 27(57) |
| Approvable(%) | 46(46) | 18(37) | 23(34) | 22(33) | 16(34) |
| Not Approvable(%) | 27(27) | 15(31) | 21(31) | 18(27) | 4( 9) |
| Denials | 0 (0) | 4 (8) | 0 (0) | 0( 0) | 0( 0) |
| Approval Decision Subtotal | 100 | 49 | 68 | 66 | 47 |
| Total PMA Actions | 364 | 332 | 323 | 354 | 249 |
| Average Review Time (days) for Approvals[b] | | | | | |
| FDA | 199 | 146 | 328 | 374 | 276 |
| Non-FDA | 87 | 40 | 109 | 78 | 81 |
| Total | 285 | 186 | 437 | 452 | 357 |
| Number under Review at End of Period[c] | | | | | |
| Active[d] | 49 | 87 | 94 | 67 | 69 |
| (Active and overdue) | (2) | (36) | (45) | (22) | (26) |
| On hold[e] | 86 | 77 | 56 | 72 | 56 |
| Total | 135 | 164 | 150 | 139 | 125 |

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

b/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (*21 CFR Part 814*). Under this regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock.

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

d/ FDA responsible for processing application.

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

**Table 3. PMA Supplements**
**FY 91 - FY 95**

| Action | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
|---|---|---|---|---|---|
| Number Received | 593 | 606 | 395 | 372 | 499 |
| PMA Supplement Actions | | | | | |
| Panel Track Filing Decisions[a] | | | | | |
| Filed(%) | 5(38) | 4(27) | 1 (10) | 3(60) | 4(0.8) |
| Not Filed(%) | 8(62) | 11(73) | 6 (90) | 2(40) | 1(0.2) |
| Other(%) | 0 (0) | 0 (0) | 0 (0) | 0 ( 0) | 0( 0) |
| Filing Decision Subtotal | 13 | 15 | 7 | 5 | 5 |
| Review Activities[a] | | | | | |
| Major Deficiencies | 14 | 2 | 5 | 1 | 3 |
| Minor Deficiencies | 0 | 0 | 0 | 0 | 1 |
| Other[b] | 251 | 196 | 251 | 219 | 147 |
| Review Activities Subtotal | 265 | 198 | 256 | 220 | 151 |
| Approval Decisions | | | | | |
| Panel track approvals(%)[c] | 2 (1) | 1 (1) | 2 (1) | 3( 1) | 3( 1) |
| Nonpanel track approvals(%) | 478(64) | 393(62) | 352(62) | 382(65) | 432(73) |
| Approvable(%) | 138(18) | 120(18) | 91(16) | 95(16) | 78(13) |
| Not approvable(%) | 134(18) | 122(19) | 124(21) | 104(18) | 75(13) |
| Approval Decision Subtotal | 752 | 636 | 569 | 584 | 588 |
| Total PMA Supplement Actions | 1,030 | 849 | 832 | 809 | 744 |
| Average Review Time (days) for Approvals[d] | | | | | |
| FDA | 111 | 113 | 168 | 253 | 179 |
| Non-FDA | 32 | 22 | 35 | 42 | 49 |
| Total | 143 | 135 | 203 | 295 | 228 |
| Number under Review at End of Period[e] | | | | | |
| Active[f] | 206 | 341 | 346 | 243 | 226 |
| (Active and overdue) | (1) | (98) | (173) | (110) | (49) |
| On hold[g] | 133 | 144 | 119 | 133 | 151 |
| Total | 339 | 485 | 465 | 376 | 377 |

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

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

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

(Continued on next page.)

**Table 3. PMA Supplements**
**FY 91 - FY 95**

(Continued from previous page.)

d/ Average review times are calculated under the Premarket Approval of Medical Devices Regulation (21 *CFR* Part 814). Under this regulation, the review clock is *reset* upon FDA's receipt of a "major amendment" or a response to a "refuse to file" letter. Thus, average review time, unlike average elapsed time, *excludes* all review times that occurred prior to the latest resetting of the clock.

e/ The 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.

f/ FDA responsible for processing application.

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

**Table 4. Original IDEs**
**FY 91 - FY 95**

| Action | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
|---|---|---|---|---|---|
| Number Received | 213 | 229 | 241 | 171 | 214 |
| Number of Decisions | | | | | |
| Approved | 72 | 68 | 60 | 47 | 109 |
| Not approved | 141 | 130 | 166 | 109 | 81 |
| Other[a] | 7 | 17 | 22 | 18 | 20 |
| Total | 220 | 215 | 248 | 174 | 210 |
| Percent (%) of Approvals made during first review cycle[b] | 34 | 34 | 27 | 30 | 57[d] |
| Average FDA Review Time (days) | 29 | 30 | 28 | 29 | 29 |
| Percent (%) of Decisions made within 30 Days | 99 | 97 | 97 | 95 | 92[e] |
| Number under Review at End of Period[c] | 12 | 21 | 14 | 11 | 15 |
| Number Overdue at End of Period | 1 | 0 | 3 | 0 | 0 |

a/ Includes deletions, withdrawals, and other administrative actions not resulting in an approval/disapproval decision.
b/ Based on "approved" and "not approved" decisions only.
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/ During the first half of FY 95 this percentage was 49%; during the second half of FY 95, after the establishment of new policies and procedures, it rose to 65%.
e/ In October 1995, ODE moved its offices from Piccard Drive to Corporate Boulevard in Rockville, Maryland. ODE accepted premarketing submissions during the 14-day moving period but added 2 weeks to the due dates of IDEs. This 2-week delay is reflected in the percent of decisions made within the 30 days for original IDEs and amendments. This policy was announced in two notices in the *Federal Register* of October 14, 1994 (pg. 52170) and November 29, 1994 (pg. 60092).

**Table 5. IDE Amendments**
**FY 91 - FY 95**

| Action | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
|---|---|---|---|---|---|
| Amendments Received[a] | 283 | 297 | 320 | 254 | 210 |
| Decisions on Amendments | | | | | |
| Approved(%) | 133(46) | 127(43) | 93(29) | 109(43) | 106(50) |
| Not approved (%) | 80(28) | 92(31) | 131(40) | 68(27) | 38(18) |
| Other (%)[b] | 74(26) | 78(26) | 100(31) | 77(30) | 69(32) |
| Total | 287 | 297 | 324 | 256 | 213 |
| Average FDA Review Time (days) | 23 | 24 | 25 | 24 | 22 |
| Percent (%) of Decisions made within 30 Days | 99 | 99 | 96 | 97 | 92[e] |
| Average Approval Time (days) for IDEs with Amendments | | | | | |
| FDA time | 71 | 79 | 83 | 83 | 70 |
| Non-FDA time | 118 | 109 | 129 | 159 | 162 |
| Total time[c] | 189 | 188 | 212 | 242 | 232 |
| Number of Amendments per Approved IDE | 1.8 | N/A | 2.2 | 2.3 | 1.8 |
| Amendments under Review at End of Period[d] | 25 | 21 | 16 | 11 | 8 |
| Amendments Overdue at End of Period | 0 | 1 | 2 | 0 | 0 |

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

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

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

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

e/ In October 1995, ODE moved its offices from Piccard Drive to Corporate Boulevard in Rockville, Maryland. ODE accepted premarketing submissions during the 14-day moving period but added 2 weeks to the due dates of IDEs. This 2-week delay is reflected in the percent of decisions made within the 30 days for original IDEs and amendments. This policy was announced in two notices in the *Federal Register* of October 14, 1994 (pg. 52170) and November 29, 1994 (pg. 60092).

**Table 6. IDE Supplements**
**FY 91 - FY 95**

| Action | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
|---|---|---|---|---|---|
| Number Received | 3,647 | 3,644 | 3,668 | 3,020 | 3,171 |
| Number of Decisions | 3,705 | 3,469 | 3,814 | 3,070 | 3,181 |
| Average FDA Review Time (days) | 21 | 23 | 24 | 23 | 22 |
| Percent (%) of Decisions made within 30 Days | 99 | 99 | 97 | 98 | 98 |
| Number under Review at End of Period[a] | 189 | 359 | 213 | 160 | 149 |
| Number Overdue at End of Period | 0 | 4 | 8 | 1 | 0 |

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

**Table 7. 510(k)s**
**FY 91 - FY 95**

| Action | FY 91 | FY 92 | FY 93 | FY 94 | FY 95 |
|---|---|---|---|---|---|
| Number Received | 5,770 | 6,509 | 6,288 | 6,434 | 6,056 |
| Number of Decisions | | | | | |
| Substantially equivalent | 4,294 | 3,776 | 4,007 | 5,498 | 5,594 |
| Not substantially equivalent | 122 | 130 | 135 | 135 | 101 |
| Other[a] | 951 | 956 | 931 | 1502 | 2,253 |
| Total | 5,367 | 4,862 | 5,073 | 7,135 | 7,948 |
| Percent(%) not substantially Equivalent[b] | 2.8 | 3.3 | 3.3 | 2.4 | 1.8 |
| Average Review Time (days) | | | | | |
| FDA time[c] | 81 | 102 | 162 | 184 | 137 |
| Total time[d] | 102 | 126 | 195 | 216 | 178 |
| Median Review Time (days) | | | | | |
| FDA time[c] | 73 | 88 | 144 | 134 | 91 |
| Total time[d] | 82 | 90 | 164 | 155 | 102 |
| Percent (%) of Decisions made within 90 Days, based on | | | | | |
| FDA time[e] | 100[i] | 94 | 46 | 45 | 62 |
| Total time[d] | 57 | 45 | 20 | 27 | 36 |
| Number under Review at End of Period[f] | | | | | |
| Active[g] | 1,402 | 2,599 | 3,822 | 2,414 | 1,486 |
| (Active and overdue) | 0 | (331) | (1894) | (460) | (9) |
| On hold[h] | 889 | 1,352 | 1,335 | 1,960 | 964 |
| Total | 2,291 | 3,951 | 5,157 | 4,374 | 2,450 |

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

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

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

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

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

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

g/ FDA responsible for processing notification.

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

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

**Table 8. Major Submissions Received**
**FY 85 - FY 95**

| Type of Submission | 1985 | 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Orig. PMAs | 97 | 69 | 81 | 96 | 84 | 79 | 75 | 65 | 40 | 43 | 39 |
| PMA Supp. | 393 | 478 | 700 | 727 | 810 | 660 | 593 | 606 | 395 | 372 | 499 |
| Orig. IDEs | 204 | 206 | 218 | 268 | 241 | 252 | 213 | 229 | 241 | 171 | 214 |
| IDE Amend. | N/A | 365 | 265 | 316 | 271 | 288 | 283 | 297 | 320 | 254 | 210 |
| IDE Supp. | 2,457 | 2,884 | 2,836 | 3,391 | 3,038 | 3,043 | 3,647 | 3,644 | 3,668 | 3,020 | 3,171 |
| 510(k)s | 5,254 | 5,063 | 5,265 | 5,536 | 7,022 | 5,831 | 5,770 | 6,509 | 6,288 | 6,434 | 6,056 |
| Total | 8,974 | 8,974 | 9,365 | 10,334 | 11,466 | 10,153 | 10,581 | 11,350 | 10,952 | 10,293 | 10,189 |

**Table 9. Major Submissions Completed**
**FY 85 - FY 95**

| Type of Submission | 1985 | 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Orig. PMAs | 37 | 72 | 46 | 46 | 56 | 47 | 27 | 12 | 24 | 26 | 27 |
| PMA Supp. | 377 | 477 | 565 | 652 | 519 | 700 | 479 | 394 | 354 | 385 | 434 |
| Orig. IDEs | 201 | 213 | 224 | 260 | 245 | 248 | 220 | 215 | 248 | 174 | 210 |
| IDE Amend. | 361 | 330 | 253 | 327 | 280 | 270 | 287 | 297 | 324 | 256 | 213 |
| IDE Supp. | 2,190 | 3,599 | 2,784 | 3,405 | 3,023 | 2,968 | 3,705 | 3,469 | 3,814 | 3,070 | 3,181 |
| 510(k)s | 5,095 | 5,359 | 4,992 | 5,513 | 6,136 | 6,197 | 5,367 | 4,862 | 5,073 | 7,135 | 7,948 |
| Total | 8,261 | 10,050 | 8,864 | 10,203 | 10,259 | 10,430 | 10,085 | 9,249 | 9,837 | 11,045 | 12,013 |

N/A - Not available.

## APPENDIX A. ODE GUIDANCE DOCUMENTS
## Fiscal Year 1995

All ODE guidance documents are available from DSMA (HFZ-220) on the Center's Electronic Docket, a computer-based bulletin board system, via telefax and in hard copy at: ELECTRONIC DOCKET (BBS): (800) 252-1366 or (301) 594-2741; FACTS-ON-DEMAND (telefax): (800) 899-0381 or (301) 827-0111; MAIL: 1350 Piccard Drive, Rockville, Maryland 20850-4307; or, VOICE: (800) 638-2041 or (301) 443-6597.

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

  Use of International Standard ISO-10993. This purpose of this policy, issued on May 1, 1995, is to replace ODE General Program Memorandum G87-1 entitled "Tripartite Biocompatibility Guidance" with the ISO Standard "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The new policy includes an FDA-modified matrix that designates the type of testing needed for various medical devices and a flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s."

  Goals and Initiatives for the IDE Program. The purpose of this policy, issued on July 12, 1995, is to establish procedures for the efficient review of IDEs and to identify performance goals for the IDE Program.

  Implementation of the FDA/HCFA Interagency Agreement. The purpose of this policy, issued September 15, 1995, is to establish procedures for fulfilling FDA's responsibilities as defined in the FDA/HCFA Interagency Agreement (IA) pertaining to the reimbursement of investigational devices.

  Availability of Investigational Devices. The purpose of this May 10, 1995 memorandum was to reaffirm ODE's policy regarding continued availability of investigational devices during the intervening period between completion of the clinical study and approval of the marketing application.

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

  Coronary and Cerebrovascular Guidewire. In January 1995, DCRND revised the Coronary and Cerebrovascular Guidewire Guidance. The purpose of this revision was to eliminate the absolute requirement for clinical data on guidewires less than 0.014" in diameter. A well designed and controlled animal study may be substituted for clinical data.

  Percutaneous Transluminal Coronary Angioplasty (PTCA) Package Insert Template. On February 7, 1995, DCRND issued a PTCA Package Insert Template. The purpose of the template was to outline the appropriate content/format of the package insert for PTCA catheters.

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

  Human Chorionic Gonadotropin (hCG). On September 29, 1995, DCLD issued the Review Criteria for Assessment of human Chorionic Gonadotropin (hCG) for in vitro diagnostic devices (IVDs). This document provides guidance about the information to clear tests to detect pregnancy intended for use at home, in clinical laboratories, and at physicians' office laboratories.

  Drugs of Abuse Assays. On September 29, 1995, DCLD issued the Review Criteria for Assessment of in vitro diagnostic devices (IVDs) for Drugs of Abuse Assays using various methodologies. This document provides guidance about the information needed to clear drugs of abuse assays using various methodologies.

  Primary, Secondary and Generic Reagents for Automated Analyzers. On September 29, 1995, DCLD issued the Data Required for Commercialization of Primary, Secondary, and Generic Reagents for Automated Analyzers. DCLD regulates reagents used with in vitro diagnostic (IVD) analyzers through the premarket notification process (PMN). The document provides guidance about the data to clear the devices based on conformance of labeling to 21 CFR 809.10 and review of equivalence of the performance data including sensitivity, specificity, precision, and accuracy.

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

  Ceramic Ball Hip Systems. On January 10, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notifications [510(k)] for Ceramic Ball Hip Systems. Due to the reclassification of these devices from Class III to Class II, the guidance document outlines the scientific and regulatory information for a 510(k) for these devices.

  Orthopedic Devices. On March 28, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices: The Basic Elements. This guidance document provides guidelines to the sponsors of future premarket notifications for orthopedic devices. This document outlines the administrative, scientific and regulatory information for a 510(k) application.

  Polyethylene in Orthopedic Devices. On March 28, 1995, DGRD issued a revised premarket notification [510(k)] guidance document, Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices, which discusses content and format for test data for a 510(k) for these devices.

  Femoral Stem Prostheses. On May 1, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Femoral Stem Prostheses. This guidance document outlines the important issues, concerns, content and format for test data for a 510(k) for these devices.

Modular Implant Components. On May 1, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components. This guidance document outlines the important issues, concerns, content and format for test data for a 510(k) for these devices.

Acetabular Cup Prostheses. On May 1, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Testing Acetabular Cup Prostheses. The guidance document outlines the important issues, concerns, content and format for test data for a 510(k) for these devices.

Spinal Fixation Device Systems. On July 18, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Reviewing Spinal Fixation Device Systems. This document provides the most current guidelines to the sponsors of future premarket notifications for spinal fixation systems. This document also addresses common application deficiencies and provides specific information for a 510(k) application.

Submerged (Underwater) Exercise Equipment. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment. This guidance document outlines the administrative, scientific, and regulatory information for a 510(k) for this device.

Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Electromyograph Needle Electrodes. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes. The guidance document outlined the information for a 510(k) application for this device.

Exercise Equipment. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Exercise Equipment. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for this device.

Heating and Cooling Devices. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for this device.

Therapeutic Massagers and Vibrators. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Therapeutic Massagers and Vibrators. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Powered Muscle Stimulators, Ultrasound Diathermy and Muscle Stimulators. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Muscle Stimulators, and Ultrasound Diathermy and Muscle Stimulators. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Powered Tables and Multifunctional Physical Therapy Tables. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Immersion Hydrobaths. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hydrobaths. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Communications Systems and Powered Environmental Control Systems. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Beds. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

Biodegradable Polymer Fracture Fixation Devices. On July 26, 1995, DGRD issued a Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Testing Biodegradable Polymer Fracture Fixation Devices. This guidance document outlines the administrative, scientific and regulatory information for a 510(k) for these devices.

- **Division of Dental, Infection Control, and General Hospital Devices (DDIGD) (formerly the DGRD Pilot Division)**

Dental Handpieces. In July 1995, DGRD (Pilot) drafted a guidance document for the preparation of premarket notification for dental handpieces. This draft provides guidance on the types of data that may be included in 510(k) submissions for dental handpieces.

Sharps Injury Prevention Feature Guidance. In March 1995, DGRD (Pilot) issued a revision of the February 1994 supplementary guidance on the content of Premarket Notification Submissions for Medical Devices with Sharps Injury Prevention Features. This supplemental guidance is intended to assist in assembling and organizing premarket notifications for devices incorporating a sharps injury prevention feature and the types of data that may be included in such submissions. This revision incorporates comments received during the May 1994 General Hospital and Personal Use Devices Panel Meeting including a reduction in the recommended sample size for clinical trials.

Short-Term and Long-Term Intravascular Catheter. In March 1995, DGRD (Pilot) issued a revision of the April 1993 draft guidance document on Premarket Notification Submission for Short-Term and Long-Term Intravascular Catheters. The guidance document contains a description of the administrative, scientific, and regulatory content needed for a complete 510(k) application including labeling recommendations and performance data to support surface modifications and antineedle-stick claims.

Latex Medical Gloves. In March 1995, DGRD (Pilot) issued an interim guidance document on Protein Content Labeling Claim for Latex Medical Gloves. This guidance document describes the information in a 510(k) submission to support a labeling claim related to total water extractable protein levels in latex medical gloves, i.e., latex examination and surgeon's gloves.

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

IOL PMA/IDEs. The Guidance for the Submission of PMA and IDE Applications for High and Low Power Intraocular Lenses was issued on January 6, 1995. This guidance outlines approval of IOLs outside the standard power range of +4 to +34 diopters. IOLs outside the standard power range are used for extremely myopic and hyperopic persons.

Multifocal IOL IDEs/PMAs. The draft Guidance for Multifocal Intraocular Lens IDE Studies and PMAs was issued on January 6, 1995. This guidance provides updated submission requirements for multifocal IOLs. The guidance updates and consolidates the requirements outlined in FDA's June 13, 1990; January 4 and March 4, 1991; and February 16, 1993 multifocal IOL guidance documents.

Contact Lens Care Products. The draft Premarket Notification Guidance Document for Contact Lens Care Products was issued on June 7, 1995. The re-edited guidance will serve as a special control for regulating these transitional products in Class II following reclassification.

PRK Laser IDEs/PMAs. The Guidance for Photorefractive Keratectomy (PRK) Laser Systems: IDE Studies and PMA Applications was presented for discussion at the July 20, 1995 Ophthalmic Devices Advisory Panel Meeting and numerous comments were received.

This draft guidance document provides information on the engineering, preclinical, and clinical studies needed to evaluate the safety and effectiveness of PRK lasers for their intended use. The guidance is being redrafted in response to comments and a second draft will be made available for comments during FY 96.

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

Benign Prostatic Hyperplasia. In November 1994, DRAERD updated the draft Guidance for Clinical Investigations of Devices used for the Treatment of Benign Prostatic Hyperplasia (BPH). This document combines pertinent sections of the December 9, 1991, "Draft Guidance for the Clinical Investigations of Hyperthermia Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)" and the March 26, 1993, "Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)." The clinical sections contained in the March 26, 1993, guidance document were changed slightly and these changes have been summarized at the end of the document. The preclinical testing sections from the December 9, 1991, guidance document have been revised significantly based on reviews of previous Investigational Device Exemption (IDE) applications for hyperthermia and other thermal field producing devices. The purpose of this document is to: (1) alleviate some of the confusion over having two guidance documents cover one device area; (2) supersede both of the previous guidance documents; (3) provide for uniform collection of data for all devices used to treat BPH; and (4) revise certain clinical testing requirements while maintaining the scientific validity of the study.

Mechanical Lithotriptors and Stone Dislodgers. In November 1994, DRAERD issued a draft 510(k) Checklist for Mechanical Lithotriptors and Stone Dislodgers used in Gastroenterology and Urology. Stone dislodgers are intended to be used during urological and/or gastroenterological procedures to endoscopically grasp, manipulate and remove calculi and other foreign objects. Mechanical lithotriptors are intended to grasp, crush and remove urinary and/or biliary stones. The purpose of this 510(k) checklist is to identify the type of information that should be provided in a premarket notification 510(k) for mechanical lithotriptors and stone dislodgers used in gastroenterology and urology.

Conditioned Response Enuresis Alarms. In November 1994, DRAERD issued a draft 510(k) Checklist for Conditioned Response Enuresis Alarms (condition response). This guidance document is intended to assist in the preparation of a premarket notification 510(k) application.

Condom Catheters. In February 1995, DRAERD issued a draft 510(k) Checklist for Condom Catheters. This guidance is intended to assist in the preparation of a premarket notification 510(k) submission for a condom catheter, an accessory to a urosheath type incontinence device.

External Penile Rigidity Devices. In March 1995, DRAERD issued a draft Guidance for the Content of Premarket Notifications for External Penile Rigidity Devices. An external penile rigidity device is used in the treatment of erectile dysfunction. The purpose of this guidance document is to identify the type of information that should be provided in a premarket notification 510(k) for external penile rigidity devices.

Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter). In March 1995, DRAERD issued a draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter). This guidance document addresses the preparation of premarket approval (PMA) applications for the Artificial Urinary Sphincter (AUS), a device intended for the treatment of urinary incontinence in males and females.

Endoscopes Used in Gastroenterology and Urology. In March 1995, DRAERD issued a draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology. The purpose of this guidance document is to identify the types of information that should be provided in a premarket notification 510(k) for endoscopes intended for use in gastroenterology and urology.

Penile Rigidity Implants. In May 1995, DRAERD issued a draft Guidance for the Content of Premarket Notification for Penile Rigidity Implants. The purpose of this guidance document is to identify the type of information that should be provided in a premarket notification 510(k) for penile rigidity implants.

Menstrual Tampon. In May 1995, DRAERD issued a Draft Guidance for the Content of Premarket Notification for Menstrual Tampon. The purpose of this guidance document is to outline the content for a premarket notification 510(k) submission, particularly the critical aspects, for menstrual tampons.

Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence. In June 1995, DRAERD issued a draft Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence. The purpose of this 510(k) checklist is to identify the type of information that should be provided in a premarket notification 510(k) for nonimplanted electrical continence devices.

Latex Condom. In June 1995, DRAERD issued a draft Information for a Latex Condom 510(k) Submission for Obstetrics/Gynecology Branch (original was issued in July 1994). The purpose of this guidance document is to identify the type of information that should be provided in a premarket notification 510(k) for latex condoms.

Male Condoms Made from New Material. In June 1995, DRAERD issued an updated guidance document, Testing Guidance for Male Condoms Made from New Material (origi-

nal, July 1994). The purpose of this guidance document is to identify the type of information that should be provided in a premarket notification 510(k) for male condoms made from a new material.

Endoscopic Light Sources Used in Gastroenterology and Urology. In June 1995, DRAERD issued a draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology. The purpose of this 510(k) checklist is to identify the type of information that should be provided in a premarket notification 510(k) for endoscopic light sources used in gastroenterology and urology.

Urological Irrigation System and Tubing Set. In August 1995, DRAERD issued a draft 510(k) Checklist for Urological Irrigation System and Tubing Set. The purpose of this 510(k) checklist is to identify the type of information that should be provided in a premarket notification 510(k) for a urological irrigation systems and/or tubing set.

Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology. In August 1995, DRAERD issued a 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology. The purpose of this 510(k) checklist is to identify the type of information that should be provided in a premarket notification 510(k) for electrosurgical units (ESU) and accessories used in gastroenterology and urology.

Hysteroscopes & Laparoscopes, Insufflators and Other Related Instrumentation, Submission Requirements for a 510(k). There are now 3 parts to this guidance: (a) the March 1994 guidance is the original guidance; (b) in May 1995, DRAERD issued a 510(k) guidance for 2-D Laparoscopes, an SE Comparison, and this part completely replaced the information on insufflators; (c) in August 1995, DRAERD issued a checklist for what is recommended for premarket notification 510(k)s for hysteroscopes and laparoscopes, but does not completely replace the original document. DRAERD is working on a guidance document for "Hysteroscopes and Gynecologic Hysteroscopes." This will be a companion to the SE comparison chart and will completely replace the March 15, 1994 document.

## APPENDIX B. ODE PUBLICATIONS
## Fiscal Year 1995

The following is a bibliography of articles and abstracts prepared by the ODE staff and published or presented during FY 95.

Journal, Newsletter Articles and Book Chapter

Bazaral, M.G. and Ciarkowski, A. Food and Drug Administration Regulations and Computer-Controlled Infusion Pumps. *International Anesthesiology Clinics*, Winter Quarter, 1995.

Ciarkowski, A.A. Regulatory Issues of Extracorporeal Life Support (ECLS) Devices. In *Extracorporeal Life Support, Extracorpeal Life Support Organization*, Ann Arbor, MI, 1995, Chapter 34.

Flack, M. Substantiating Hearing Aid Benefit Claims. *Audiology Today*, 7(3):21-22, May/ June 1995.

Flack, M. Hearing Aid Market Developments. *Current Opinion in Otolaryngology and Head and Neck Surgery*, 3:332-36, October 1995.

Krawczyk, C. Glaucoma Drainage Devices and the FDA. *Ophthalmology - The Journal of the American Academy of Ophthalmology*, 102(11):1581-82, November 1995.

Picciolo, G.L., Durfor, C., and Christensen, L. Tissue Engineering Issues Highlight World Biomaterials Congress. *Biomaterials Forum Newsletter*, September-October issue.

Abstracts

Durfor, C. Preclinical Issues for Biosynthetic Skin Products. IBC Meeting, Soft and Hard Tissue Engineering and Repair, Washington, DC, August 10, 1995.

Gantt, G. Clinical Trials for Skin Products: Effectiveness and Endpoints. IBC Meeting Soft and Hard Tissue Engineering and Repair, Washington, DC, August 10, 1995.

Kues, H.A., D'Anna, S.A., Johnson, M.A., Green, W.R., and Monahan, J.C. Retinal Damage Following Repeated Exposure to Pulsed 1.25 GHz at an Average Local SAR of 4mW/g. Bioelectromagnetics Annual Meeting, Boston, MA, June 1995.

Scott, P. and Runner, S. FDA and the Regulation of Clinical Trials for Endosseous Implants. American Academy of Periodontology Joint Symposium on Clinical Trial Design and Analysis in Periodontics, NIH, Bethesda, MD, January 30-February 2, 1996.

Singleton, D.G. and Torres-Cabassa, A. The FDA and Regulation in Clinical Trials on Periodontal Regeneration. American Academy of Periodontology Joint Symposium on Clinical Trial Design and Analysis in Periodontics, NIH, Bethesda, MD, January 30-February 2, 1996.

Torres-Cabassa, A. Combination Products of BMP, Collagen, and Bone: Safety and Effectiveness Issues Update. IBC, Soft and Hard Tissue Engineering and Repair, Washington, DC, August 10, 1995.

Other

Baker, K. and Cygnarowicz, T. Fact Sheet about FDA and Clinical Trials/Hearing Aid Research. Hearing Aid Research and Development Conference, NIH, Bethesda, MD, September 11-13, 1995.

# APPENDIX C. ODE STAFF ROSTER
## Fiscal Year 1995

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# APPENDIX D. ODE ORGANIZATIONAL CHART