



CDRH Annual Report Fiscal Year 1997



FDA · CDRH Annual Report Fiscal Year 1997

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

TO CONTACT FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

- Internet: <http://www.fda.gov/cdrh/index.html>
For directories, general information, guidance documents, cleared 510(k)s, FactsOnDemand Index, Federal Register announcements, workshop announcements, Third Party Program information, etc.
- Facts-On-Demand: 800-899-0381 or 301-827-0111
To obtain key CDRH documents automatically by fax.

- Division of Small Manufacturers Assistance: 800-638-2041 or 301-443-6597
Fax 301443-8818, e-mail address: DSMO@CDRH.FDA.GOV
For general information on medical device requirements.



9200 Corporate Boulevard
Rockville, MD 20850

October 14, 1997

Dear President/CEO:

I'm especially pleased to send you this year's annual report.

As you'll see, the report highlights two important "good news" messages. First, we have eliminated the backlogs of new product submissions. There are no overdue applications in the Center—a dramatic change from just a few years ago. Second, our turnaround times for processing these submissions—510(k)s, IDEs, PMAs and PMA supplements—have improved across the board. That means new devices are getting to patients more promptly, and that manufacturers can count on a more predictable review process. We also have clear improvements in our Medical Device Reporting and Quality Systems programs.

But the good news must be tempered with reality. Our center, like most of the government, faces the challenge of getting the job done in the face of rising costs and shrinking resources. And so we must seek more efficient ways to fulfill our mission. That's why we're devoting so much thought and energy to "re-engineering" the device program, forcing ourselves to take a fresh look at why we're here and what we're supposed to accomplish. Working closely with the industry, we're trying to refocus our efforts on those tasks that have maximum impact on public health. You'll find a brief summary of our re-engineering progress in this report, and a more detailed accounting on our web page (<http://www.fda.gov/cdrh/index.html>).

As the fiscal year closes, Congress is working on legislation that may somewhat reshape our program. Should this occur, we'll give top priority to implementing the new law, and will let you know about how it may affect your interactions with us.

In the meantime, I'd appreciate hearing from you. Enhanced communication between our program and the industry—from meetings with individual firms to discuss premarket submissions to nationally broadcast video

teleconferences-has been a key factor in improving our performance. So let me know about your experiences and your perceptions of how we're doing. And please give me your ideas about how we can do things better. After all, we share a common goal: to make available the safest, most effective medical devices possible, and to give practitioners and patients the information they need to derive the best results from these products.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

Introduction

High U.S. premarket standards enhance confidence...

This report, which documents four years of steady progress in FDA's medical device program, must be understood in context. The United States sets the world standard in premarket device review. Our investment in new product assessment gives American consumers, physicians and third party payers an unparalleled level of confidence in medical devices from U.S. firms. Our review system does more than simply assure that products are well designed and manufactured-it also provides valuable information on how devices can best be used, and what results physicians and consumers can expect.

...but this necessitates a tradeoff

There is an inherent tradeoff in the U.S. review system. On the one hand, requiring and independently reviewing scientific data on how to use new devices and on their risks and benefits is a potent force in keeping unsafe or ineffective products off the market. On the other hand, it takes time and effort for manufacturers to develop the data and for FDA to review it. As a result, marketing approval in the U.S. often is not the first in the world. Many products are first sold in countries with minimal or nascent clinical data review systems.

The goal: rigor and speed

This tradeoff-between the effort necessary to derive scientific information on a new device and its early marketing-sets the framework for the Center's primary goal in premarket review: to retain scientific rigor, but to streamline the process so as to make rapidly available the benefits of new products.

A two-step approach toward reaching that goal:

Step 1: Increasing our efficiency

The first step has been performance enhancement, or improving the efficiency with which we carry out existing tasks-in the case of premarket review, reducing the time it takes to process submissions. We have made significant strides in this area and will continue to do so in the future. Our progress to date is summarized in this report.

Step 2: re-engineering the program

The second (and more difficult) step, now also underway, is process improvement and reengineering. Here we are going beyond simply streamlining existing tasks. Looking at the program through the eyes of our various stakeholders, we are asking ourselves where our efforts might be refocused to maximize our impact on public health. This means challenging old assumptions and asking ourselves where fundamental changes in our approach might work better for manufacturers and yield equivalent (or better) public health protection at less cost to the taxpayer.

...to cope with expanding technology and limited resources... We are engaging in this process of basic re-engineering-"reinventing" our program-partly out of sheer necessity. As new technologies flourish, we are seeing an explosive growth in the complexity of many new medical devices. At the same time, the resources available to us are shrinking, not growing. The result? Even if we achieve greater efficiency in carrying out existing tasks, we will soon be overtaken by our increasing workload. We must seek not only to do our present job better, but to redefine that job.

...by re-setting priorities based on risk In performing this re-appraisal, we have committed ourselves to a risk-based approach to our work. We are focusing our resources on high-risk, high-impact products. And we are putting less emphasis on those areas posing lower risk to the public, where our direct involvement adds less value.

Progress in Accomplishing Today's Tasks: The FY 97 Statistics

The past year has seen dramatic improvement in the speed and efficiency with which we evaluate new medical devices before they are marketed, while maintaining a strong scientific basis for these decisions.

- We reviewed PMAs in only 2/3 the time it has taken in past years.
- By year's close we had taken action on all applications that were due.
- We had faster reviews in all categories.

Here are some more details:

Premarket Approval Applications (PMAs)

Background A Premarket Approval Application (PMA), represents the highest level of regulatory scrutiny applied to medical devices. A PMA is required for any new device that is not substantially equivalent to an existing one. The manufacturer submits complete scientific and clinical data on the device's safety and effectiveness. If FDA judges that the data establish the product is reasonably safe and effective, the PMA is approved.

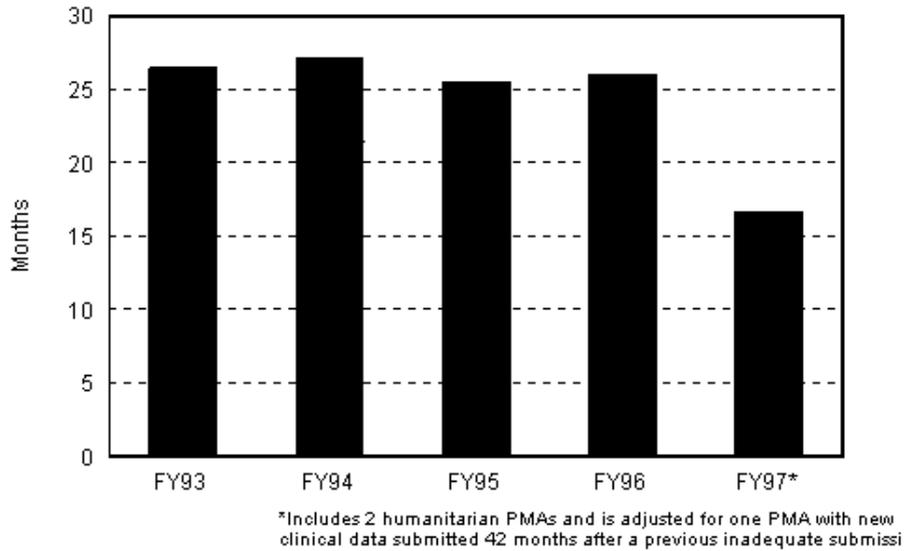
The PMA backlog is gone... We have eliminated the PMA backlog, which stood at 17 last year and peaked at 45 in fiscal year 1993.

...more PMAs are being approved... In Fiscal Year 1997, we approved 48 PMAs, the highest number since Fiscal Year 1989. Included this year are the first two Humanitarian Device PMAs for fetal bladder stents to treat urinary tract obstruction in unborn infants. Eighteen of this year's approvals represented new technologies or major advances in patient care. These include a deep brain stimulator to relieve essential tremor in Parkinson's disease; a nerve stimulator to treat intractable seizures in epilepsy; a multifocal intraocular lens that will give better near vision to people who have had cataract surgery; an implant that will restore hand grip to certain quadriplegic patients; a test that can help predict organ rejection in transplant patients by monitoring levels of an immune modulator; the first laser system for treating tooth decay; and a temporary skin substitute for severe burns.

...and more quickly We're not only approving more PMAs, we're approving them more quickly. Average total review time (including all cycles) for Fiscal Year 1997 was 16.6

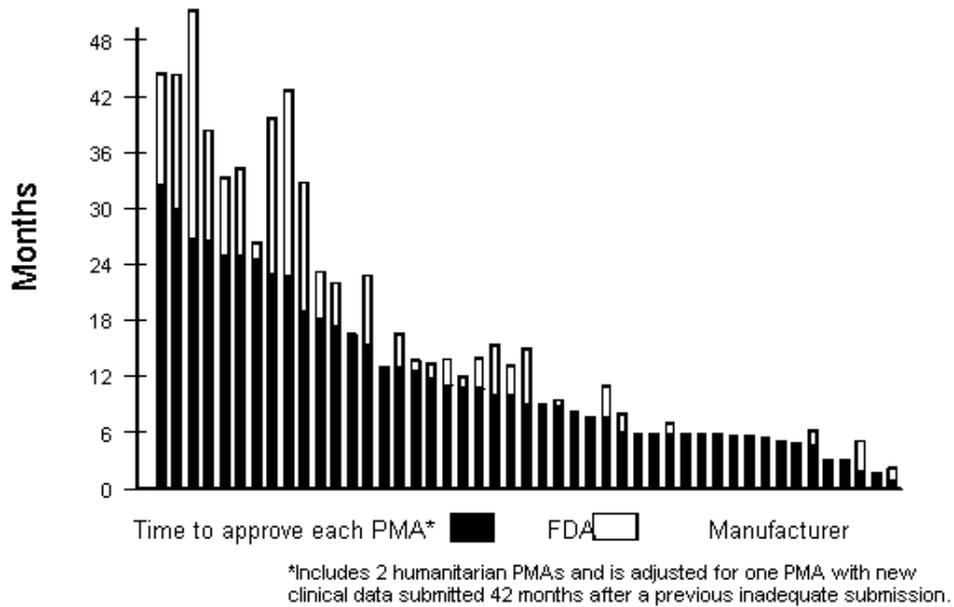
months, compared to 25.9 months in Fiscal Year 1996-more than one-third faster.

PMA Average Total Time



In Fiscal Year 1997 we approved 17 PMAs-35 percent of the total-in 180 FDA review days or less. We approved over 60 percent of them in 12 months or less of FDA review, and over 80 percent in 18 months or less of FDA review.

FY 1997 Individual PMAs



Investigational Device Exemptions (IDEs)

Background

An Investigational Device Exemption (IDE) is required for clinical investigation of a new device if it poses a significant risk. IDEs are the mechanism through which

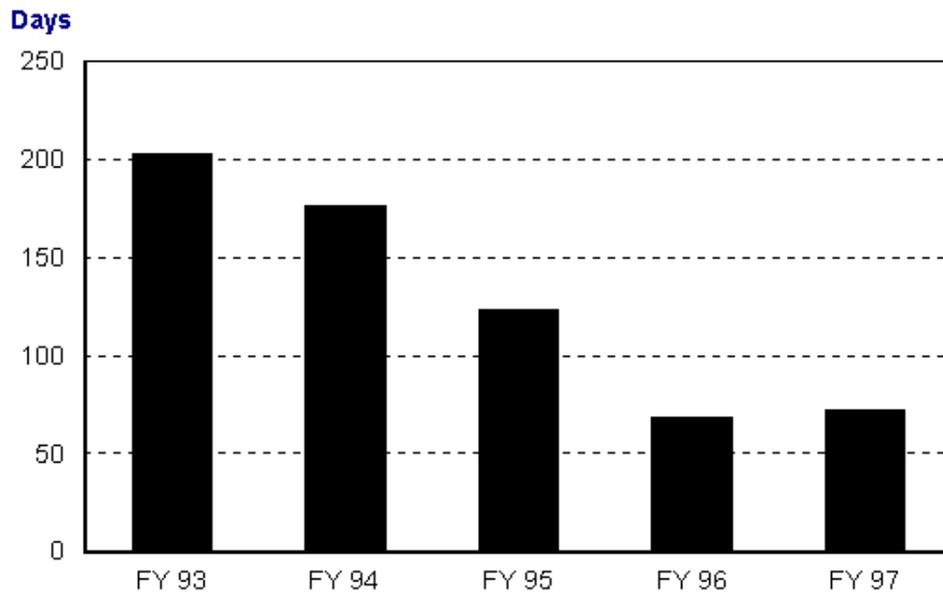
FDA assures that human subject protections are in place when manufacturers conduct clinical trials. The results of such clinical trials provide the data submitted in PMAs to establish the device's safety and effectiveness. FDA grants approval of the IDE after ascertaining that the study is well designed to elicit the desired information and that safety and ethical issues have been addressed.

Better communication with manufacturers...

In the past, FDA's evaluation of IDE submissions has often been very time consuming, requiring extensive correspondence on the part of both manufacturers and the agency. Worse still, sometimes this meant expensive mid-course corrections in clinical studies as manufacturers came to understand what needed to be done. We have recently worked more closely with device manufacturers on their IDE submissions. As a result, we have dramatically shortened the time until studies may begin.

IDE Average Total Time

...means much faster IDE approvals...



...and a record number approved on first submission

In Fiscal Year 1997, nearly 70 percent of IDEs were approved in their first 30-day cycle. Along with last year's 73 percent, this is the highest since the inception of the IDE program.

Premarket Notifications (510(k)s)

Background

Under section 510(k) of the law, more than 90% of devices are cleared for marketing when their manufacturer demonstrates they are substantially equivalent to an already-marketed device. To do this, the company submits to FDA a "premarket notification," generally referred to as a "510(k)," in which it justifies its claim for substantial equivalence.

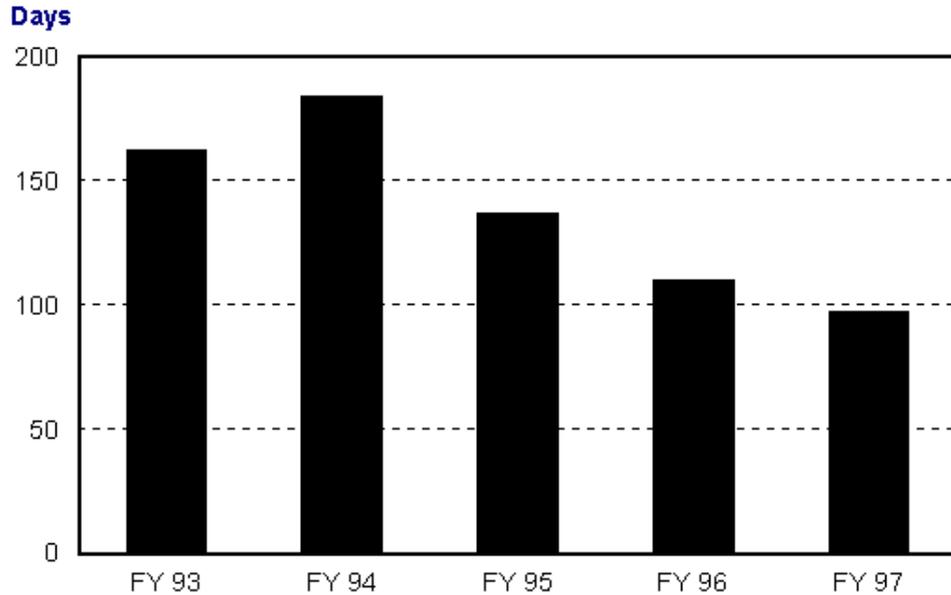
No more backlog...

Two years ago we succeeded in eliminating a massive backlog of 2,000 overdue 510(k)s.

... and reviews are getting faster

Since then, we have not only prevented the buildup of a new backlog, but have made great strides in reducing the time it takes to process these submissions. In Fiscal Year 1997, the average review time was 97 days, compared to a peak of 184 days in 1994.

510(k) Average Review Time



Improved communication with manufacturers

A common theme in all of the improvements cited above has been an intensive effort to improve our communication with manufacturers.

Reviewers interact more with sponsors throughout the premarket process...

In this dialogue, which has occurred by telephone, by video conference, and in person, we have been helping manufacturers understand what we are looking for in their submissions. We explain what information will be needed, and why, and we resolve many questions on the spot.-



We have begun sharing and discussing PMA deficiency letters before they are mailed so both the company and FDA are sure what we are asking for - and that we haven't overlooked information that has already been submitted.

...which facilitates present and

In addition to facilitating review of the present submission, such interaction and feedback increases the manufacturer's overall understanding of FDA's review process, so that submissions for future products should be improved as well.

**future
reviews**

Changes in our inspection program

**Routine quality
system
inspections
recognize
manufacturer's
needs**

Last year, working with grassroots industry organizations and FDA's field operations, we adopted a new approach to inspecting medical device manufacturers that includes three features:

- Routine inspections are preannounced and scheduled;
- Manufacturers' responses to observations made during an inspection are noted on the inspectional record; and
- When an inspection finds that effective quality systems are in place, FDA sends a letter documenting the satisfactory result.

This new program has been extremely well received by both the medical device industry and FDA field inspectors.

Our continuing commitment to timeliness and efficiency

We recognize that despite the significant improvements described above, we can further enhance our timeliness and efficiency in our premarket review and other program areas, and we are committed to doing so.

**What we will do
to
assure
continuing
improvements**

Fundamentally, our commitment to change includes:

- A continued decrease in PMA review times through comprehensive, interactive reviews that encompass not just evaluating the application but also providing input during the product development phase.
- Improving communication to patients and practitioners through better product labeling.
- Developing more and better product standards in cooperation with the industry, so that standards-based clearance of 510(k)'d products can be used more effectively and extensively.
- Working through the list of pre-1976 class III products to either reclassify them or call for PMAs to establish safety and effectiveness.
- Enhancing our understanding of how devices are performing in the real world of clinical practice, so that we and the industry know when and how to inform users about potential problems.
- Selectively directing our inspection and enforcement activities toward relatively high-risk, high-impact devices, and enhancing industry's use of design controls, the cornerstone of the new Quality Systems regulations.

**Progress in Shaping the Future:
Re-engineering the program**

**In redesigning
our
processes, we**

With the active participation of the medical device industry, health professionals and consumers, we are re-thinking the basic elements of our program, devising ways to enhance our efficiency and responsiveness. We have 13 teams-covering

consult with stakeholders more than two-thirds of our activities-working to improve and re-engineer the way the Center does it business.

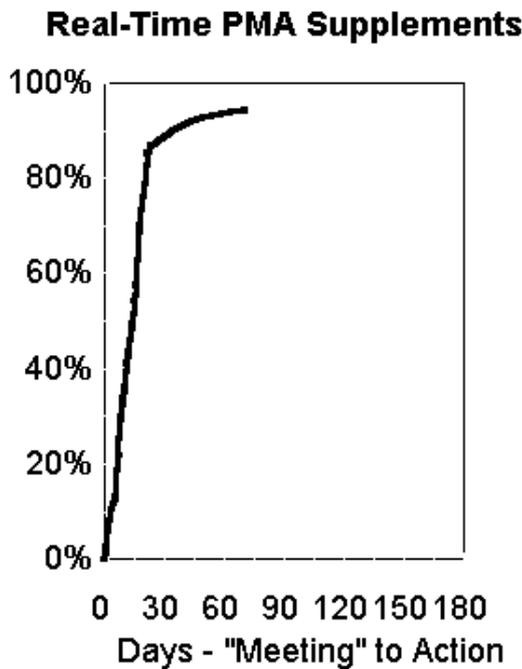
New processes are pilot tested Within the boundaries of existing legislation, and with available resources, we are testing or planning to test a number of promising new approaches in carrying out our mission.

Here are a few examples. More detailed information is available at our web site (<http://www.fda.gov/cdrh/index.html>).

"Real-time" review of PMA supplements

For certain kinds of device changes, such as labeling or product design alterations, we have pilot-tested a system of "real-time" review, in which the changes are reviewed during a meeting, teleconference or videoconference with the firm.

Some PMA supplements can be reviewed in just a few days This has already resulted in more efficient use of our staff, as well as a dramatic reduction in review time from the statutory directive of 180 days to as little as five working days. We are now expanding "real time" PMA supplement review to all premarket review branches and expect that it will be applicable to up to one-half of the 500 PMA supplements we receive every year.



Periodic summaries of adverse event reports

Individual reports are vital for unforeseen events... Under our Medical Device Reporting (MDR) system, the law requires manufacturers to submit individual reports whenever one of their devices has been involved in a serious adverse event. These individual reports are essential when the adverse event is new or unforeseen. But if it has been experienced many times in the past, or is referred to in the product's labeling, individual reports may not be necessary or even helpful.

...but periodic summaries may be suitable for anticipated events Accordingly, we are pilot testing a system in which FDA waives the usual requirement so manufacturers may use quarterly tabular summaries to submit information on adverse events that are well understood and anticipated. This should be far less time-consuming and expensive for both the manufacturer and FDA. Our long-term goal is to increase the number of lower-risk MDR reports that are summarized or entered automatically so we can redirect resources to problems that may pose a higher risk.

Decentralizing recall classification

Recall classifications are traditionally done at headquarters... Recalls of medical devices initiated by FDA are classified according to potential public health risk. This affects the actions FDA and the manufacturer take in retrieving the product-in general, the greater the potential risk, the more rigorous the required corrective action. In the past, recall classification was performed at FDA headquarters after initial review and analysis in the field offices. This was time-consuming for the agency, and slowed feedback to the manufacturer sometimes delaying effective action.

...but could be done by the FDA District Offices We are now engaged in a four-month pilot test of a new system in which four of the FDA District Offices across the U.S. will be performing recall classification largely on their own about 90% of the time, based on precedents established through similar recalls in the past. This should get recall information to manufacturers more quickly and facilitate their taking appropriate action.

Inspections of contract sterilizing firms

Contract sterilizers don't need reinspection for every product Manufacturers of sterile medical devices sometimes contract with other firms to perform the sterilization procedures. In the past, FDA would routinely inspect these contract sterilizing firms as a follow-up to inspecting the device manufacturer. Thus if the same sterilizing firm worked for several device manufacturers, it might be inspected several times in the same year.

To eliminate this "over-inspection" of sterilizing firms, we are pilot testing the use of a cross-check of previous inspections. This will help eliminate redundant FDA inspections, conserving resources for both the agency and the sterilizing firms.

Changing the 510(k) paradigm

Processing 510(k)s is time-consuming Because of the tremendous number of 510(k) submissions FDA receives each year, processing these documents has always been a particularly time-consuming task. As more national and international standards are developed on medical devices and design controls, the value of FDA's review of all the data in 510(k)s is diminishing.

Conformance to standards and design controls may allow abbreviated 510(k)s To increase our efficiency without putting the public at risk, we have proposed changes that will allow manufacturers of Class II devices whose design and manufacture conform to consensus standards to use an abbreviated format for their 510(k) submissions. Similarly, we are exploring design controls as a possible substitute for case-by-case review when a manufacturer wishes to modify a design feature of a device.

More device categories can be exempted from 510(k) Many of the products for which 510(k)'s are submitted are of such low potential risk that even this minimal level of regulatory control may be unnecessary. So we are proposing to exempt most Class I medical devices-those that pose little or no risk-from the 510(k) requirement. (Manufacturers will still be subject to facility inspections under FDA's Quality Systems regulations.) Conversely, where de facto special controls exist, we are proposing to shift some Class I devices into Class II where they fit better under the statutory scheme.

Product development protocols (PDPs)

The PMA system The present Premarket Approval Application (PMA) mechanism for approving new medical devices is often a "hands-off" system in which there is no previous

- works best for new technologies...** agreement between FDA and the manufacturer about what data are expected. This is appropriate for new products or emerging technologies where neither the manufacturer nor FDA can predict where the study results may lead.
- ...but may be needlessly time-consuming for well-understood products.** However, particularly for well-understood categories of products where the agency has received several similar PMAs, the system can be unnecessarily time-consuming. FDA must examine the data "de novo," expending resources to familiarize itself with the individual product, analyze the studies and identify possible inadequacies, and the manufacturer must re-submit information to correct for deficiencies.
- PDPs may be a more efficient alternative** Recognizing this, we are planning to pilot test the use of Product Development Protocols (PDPs) as an alternative to PMAs. Under this pilot test, FDA and the manufacturer will agree in advance on what will constitute good study design and a successful outcome. Then, when the study is completed, FDA need only check the results to see whether the previously agreed-upon criteria have been met. The PDP process should be quicker and more efficient than the PMA process, in that firms will not be making false starts on studies that may not be adequate. While this process is open to brand new types of devices, we are especially excited about its potential for products similar to ones already developed. Two firms have already begun to pilot test PDPs.

Sentinel reporting system

- Requiring all facilities to report adverse events has basic disadvantages...** FDA's early-warning system for tracking adverse events with already-marketed devices has been the Medical Device Reporting (MDR) system. This requires that every hospital and nursing home report all serious incidents to the agency and/or the manufacturer. This system has several intrinsic problems: the huge volume of reports that FDA must amass and analyze, the basic reluctance of many medical facilities to file reports, and the erratic quality of many of these reports.
- ...that may be overcome by using a fixed sample of facilities** As an alternative to the MDR system, we are proposing to pilot-test a "sentinel" system, in which a fixed sample of hospitals and other medical facilities across the nation would report to us in depth about device problems. The resulting data would be extrapolated to reflect national trends.

Summary

During Fiscal Year 1997 we achieved substantial improvement in the timeliness and responsiveness of all operational areas of our program-premarket review, postmarket surveillance and enforcement. We also began to prepare for a future of limited resources and expanding workload by focusing our program on high-risk areas and by pilot-testing new, more efficient methods of fulfilling our mission.

We believe that by attacking both areas simultaneously-enhancing today's performance while streamlining tomorrow's tasks-we are helping to assure our relevance and viability in the years to come.

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

Center for Devices and Radiological Health / CDRH