Promoting and
Protecting the Public
Health

Annual Report
Fiscal Year 1999

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

November 30, 1999

Dear Medical Device Manufacturer:

This year we're introducing a new, multi-tiered format for our Annual Report. The new format takes advantage of the immediacy and accessibility of the Internet, and it should enable users to quickly get only the information they need.

The first tier is represented by this letter, which will briefly touch on a few of the most significant CDRH activities for Fiscal Year 99. For those interested in more complete coverage of our programs, the next tier is a comprehensive CDRH report, which you will find on our website, http://www.fda.gov/cdrh/annual/fy99rpt.pdf. Within that report you will find links to the final tier: other CDRH websites that provide even greater detail on certain specific programs and activities. So you can dig as deeply and selectively as you like. And since the websites are updated as needed, the information should be more current than in the conventional yearly paper report. I hope you find the new format helpful.

The Y2K issue

When it comes to special issues, nothing was more important to us over the past year than helping to assure users and consumers that medical devices are Y2K compliant, and thus that healthcare delivery and patient safety will not be compromised as we enter the new millennium. As I've said in earlier correspondence, I'm pleased with the cooperation we've received from the device industry in making information available to users, and in assuring the Y2K compliance and continued availability of their products.

FDAMA

Another top priority for us in FY99 was vigorous implementation of FDAMA. We're determined to avoid the kinds of delays that occurred with the Safe Medical Device Amendments of 1990, and so our FDAMA motto has been "On Track, On Time." And as you'll see in the full report, we're living up to that mandate.

Premarket Activities

In the product review area, our goal over the past few years has been prompt decisions based on sound science, and as we've shown in the full report, we're continuing to meet that goal. For example, review times for 510(k) submissions during FY 99 were the lowest in nearly a decade. At the same time, we maintained last year's faster review times for Premarket Approval Applications (PMAs)—and acted on PMA supplements at a near-record pace—despite receiving more of these submissions than in any fiscal year since the early 1990s. I foresee no slowdown in the pace of our product review program as a result of management changes in our Office of Device Evaluation. As many of you know, the Office Director position is now vacant, but I expect that it will be filled promptly, and that the new director will maintain the excellent track record we've established.

Postmarket Activities

In the postmarket area, we've been exploring ways to convert from a universal reporting system for device users (as exemplified by the MDR regulation) to a system that monitors a statistically valid subset of users, and does so in depth. As noted in the full report, we've pilot tested a system called "MeDSuN" (Medical Device Surveillance Network), and will continue to work on it in the coming year. We're also working on ways to make our Quality System inspections more effective and less time-consuming for us

and for the firm. And, as a result of our "grass-roots" program with the industry, we're pilot testing a new system that allows firms to promptly respond to problems identified during an inspection without receiving a Warning Letter.

Communicating with the Industry

Beyond letting you know about our programmatic progress, I'm also interested in devising some creative ways to improve communication between the Center and the device industry. I have two areas especially in mind.

First, we've heard that there are continued industry concerns about the proposed procedure for dispute resolution, and about implementation of the "least burdensome" provisions of FDAMA. I'd very much like to hear your concerns, and I'm particularly interested in examples of problems your company has had in either of these arenas. Please send me your examples by post, by email (Director@cdrh.fda.gov) or by fax. If you prefer to remain anonymous, you can fax your example from a public facility.

Second, I'd like your ideas on how we can communicate with the industry more directly and actively. In the past, we've provided information on our web site, through video teleconferences, and through mailings to CEOs. While these mechanisms are good avenues for getting information to you, some of them don't give you enough opportunity to provide your views to us, or may not be as timely as we would wish. We're currently considering several new ways to communicate with industry, including having manufacturers register to get e-mail from us, and pilot-testing a monthly "Talk to the Center Director" on-line, interactive, discussion. I'd like your input on whether you would find these types of forums useful, and I also invite you to provide other suggestions for mechanisms that would meet your needs.

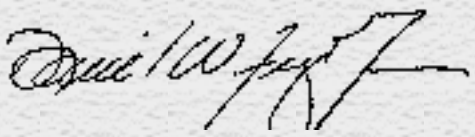
A Few Words About the Past...

Having been on the job as Center director for about six months, I can tell you that I'm immensely impressed with the quality and dedication of the CDRH staff. I told them when I arrived that I didn't intend a major shakeup of the organization, either in overall philosophy, policy or structure, because I thought that things were basically on the right track. I'm even more convinced of that now.

...and the Future

"FY 00" certainly has a strange ring to it, but I think it will bring us an even stronger medical device program—one that provides the public with the high level of protection and confidence it expects, and at the same time doesn't impose an unnecessary roadblock in the smooth transfer of new technology from laboratory to bedside.

Sincerely yours,



David Feigal, M.D., M.P.H.
Director, Center for Devices
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Premarket Program

Benefits of re-engineering and FDAMA initiatives

The Center has worked intensively in recent years to re-engineer its premarket programs and to implement the Food and Drug Administration Modernization Act of 1997 (FDAMA). These efforts have increased the efficiency of premarket reviews without compromising public health, focused review resources on devices that present the most risk, and improved communications with manufacturers. This year, review times were the shortest ever for some of our review processes, allowing safe and effective devices to reach the market more rapidly. For the third consecutive year, no submissions were overdue at the year's end.

Premarket notification (510(k))

510(k) exemptions mean fewer submissions

Since the beginning of 1998, we have exempted more than 230 well-understood, low or moderate risk (Class I or Class II) devices from 510(k) requirements. The exemptions reduced 510(k) submissions for these devices by several hundred annually. As a result of these and previous 510(k) exemptions, the total number of 510(k)s submitted in 1999 (4,458) was the lowest in any fiscal year since 1982. This has reduced industry costs and has allowed CDRH to focus more on high-impact devices.

More manufacturers use streamlined submission procedures

Manufacturers of devices still subject to 510(k) requirements are making greater use of streamlined submission procedures established by CDRH's *The New 510(k) Paradigm* re-engineering initiative (see http://www.fda.gov/cdrh/ode/parad510.html). This year, we received nearly 500 *special* or *abbreviated* 510(k)s in place of traditional 510(k)s—almost a five-fold increase in the number of streamlined submissions compared to last year. These submissions are simpler to process than traditional 510(k)s, allowing more rapid marketing clearance. FDA's review time for *special* 510(k)s, in particular, averaged just 24 days in fiscal year 1999.

Third-party reviews provide an alternative to FDA review

In November 1998—as a follow-up to our two-year pilot—we began accepting reviews of 510(k)s from qualified third parties under the Accredited Persons provisions of FDAMA. More third parties (see http://www.fda.gov/cdrh/modact/accredit.html) are qualified to conduct reviews than in the pilot, and we have increased the number of eligible moderate risk devices more than three-fold (see http://www.fda.gov/cdrh/dsma/3258.html). This year, we received 32 510(k)s with a third-party review, the most in any fiscal year since the program began, but still a very small proportion of the approximately 1200 510(k)s received this year that were eligible for third-party review. The average total elapsed time (including all time from a third party's receipt to FDA's decision) for marketing clearance was 57 days, approximately one-half the average total elapsed time for FDA's decisions on comparable 510(k)s that did not have a third-party review.

510(k)s receive more rapid review

Collectively, these initiatives contributed to further reductions in 510(k) review times. The average FDA review time (80 days) and the average total time to clearance (102 days including time while FDA review was "on hold" awaiting more information) for 510(k) decisions this year were the

shortest in nearly a decade.

Premarket approval

Significant advances improve patient care

In fiscal year 1999, we approved 45 premarket approval applications (PMAs)— representing the highest level of regulatory scrutiny applied to medical devices. This included six PMAs eligible for Humanitarian Device Exemptions and two product development protocols (PDPs), the first marketing clearances ever achieved through the PDP process. Numerous medical breakthrough devices were approved that will provide significant improvements in patient care.

Examples include:

- A transmyocardial revascularization system, in which a laser is used to create tiny holes in the myocardium in areas inaccessible to treatment by coronary artery bypass.
- A new version of a gene assay used as the basis upon which women are identified for treatment for breast cancer.
- The first two scanning excimer lasers for treating nearsightedness.
- A first-of-its-kind rapid test to detect Streptococcus pneumoniae, a bacteria that is a leading cause of pneumonia, enabling doctors to diagnose and treat the disease more quickly.
- Intrastromal corneal rings, which are removable implants for treating mild nearsightedness.
- A septal occlusion system, in which instruments are threaded through the blood vessels instead of cutting the patient open, used in a selected set of patients to close holes between the left and right sides of the heart.
- Two versions of a transvascular treatment of abdominal aortic aneurysms for people who are too ill to withstand major abdominal surgery.

Early interactions facilitate communication and review

We met with more than 20 sponsors in early collaboration meetings (i.e., *determination* or *agreement* meetings) under FDAMA provisions that were discussed in our February 1998 guidance document (see http://www.fda.gov/cdrh/modact/earlymtg.html). These meetings are intended to facilitate interaction between the agency and applicants and provide clear direction for testing and development of devices that may require clinical investigations. In addition, we received an enthusiastic response to our re-engineering initiative calling for modular review of PMAs. This initiative allows applicants to submit and receive feedback "bite-size chunks" of a PMA, rather than submitting the full set of paperwork at the end of product testing. We received more than 50 PMA "shells" this year (i.e., plans specifying the sequence of modules to be submitted), and approved eight PMAs for which modular submissions had been reviewed.

Better study designs are encouraged

We promoted better study designs through product-specific interactions, as discussed above, and

through broader initiatives, such as co-sponsoring a November 1998 workshop on Bayesian methods in clinical trials. Bayesian statistical design can result in smaller, less costly clinical studies by incorporating valid prior quantitative information into the analysis of data from a prospective clinical study. Two PMAs were approved this year based in part on Bayesian statistical analyses.

Timeliness continues to improve

We maintained last year's faster review times for PMAs—and acted on PMA supplements at a near-record pace—despite receiving more PMAs (72) and PMA supplements (556) than in any fiscal year since the early 1990's. Average total elapsed time to PMA approval was 12.5 months (similar to last year's average of 12.4 months), which was 25 percent less than the 16.6-month average for fiscal year 1997. The average total elapsed time for approval of PMA supplements was 3.9 months, the lowest since the early days of the PMA program. This decrease was due, in part, to the large proportion of supplements that were evaluated under fast-track mechanisms, such as "real-time review."

Investigational device exemptions (IDEs)

IDE reviews remain timely

IDEs are the mechanism through which FDA assures that human subjects are protected when manufacturers conduct clinical trials. As in past years, we continued to strive for a timely and interactive review process for IDE submissions this fiscal year. FDA's average review time for original IDE submissions remained stable (27 days), while the average review time for IDE supplements (20 days) was the lowest in the history of the program. Sixty-eight percent of original IDEs were approved in their first 30-day cycle, which was comparable to last year's approval rate (70 percent).

Expanded access to promising unapproved devices

Unapproved devices are normally tested in humans only by investigators participating in a clinical trial. We recognize, however, that there are legitimate circumstances in which a health care provider wishes to use an unapproved device to save a patient's life, to prevent irreversible injury, or to help a patient suffering from a serious disease or condition for which no alternative therapy exists. We have made a concerted effort—through guidance, conferences, and speeches—to make information available on the procedures that allow for such uses of unapproved devices, consistent with FDAMA's Expanded Access provisions. This has resulted in a three-fold increase in our processing of emergency use reports and individual patient access ("compassionate use") requests since FDAMA's enactment.

Modified rules reflect FDAMA changes

In November 1998, we published a final rule to modify the IDE regulation in accordance with FDAMA. Under the new regulation, sponsors of an IDE may modify the device and/or clinical protocol, without approval of a new or supplemental application, if the modifications meet certain statutory criteria and if notice is provided to FDA within 5 days of making the change. Another final rule, published that same month, modified the regulations governing humanitarian use devices (HDEs) to reduce the review timeframe for HDEs from 180 days to 75 days, and to incorporate other changes specified by FDAMA.

Regulatory Science and Standards

Cardiac Ablation

The Center developed a unique system to measure the parameters affecting the size and shape of lesions generated using radiofrequency cardiac ablation. This system allows testing the effects of applying variable electrical power and changes in blood pressure and flow. This work contributed directly to the development of a guidance document on cardiac ablation.

Interference of Cardiac Pacemakers from Cellular Telephones

CDRH developed a test system including a simulated cellular phone and a torso simulator (salt-water tank) to enable repeatable laboratory measurements of electromagnetic compatibility (EMC) between pacemakers and cellular phones. This work formed the basis of the proposed final draft EMC standard for implantable cardiac pacemakers and defibrillators by the Association for the Advancement of Medical Instrumentation.

Digital Mammography

The Center conducted significant research in both the pre-clinical and clinical stages to assist in the evaluation of digital mammography, a technique which shows promise in improving breast cancer diagnosis. CDRH scientists have investigated the physical characteristics of digital mammography systems, and have also contributed to the clinical assessment of this technique.

Ultrasound Bone Densitometry

CDRH laboratories have performed theoretical modeling and in-vitro ultrasound experiments on bone samples, resulting in three papers accepted for publication in peer reviewed journals. This research has helped develop an understanding of the accuracy of ultrasound measurements in bone, and has aided the Center in reviewing new product submissions for devices using ultrasound to measure bone density in the diagnosis of osteoporosis.

Reuse of Single-Use Devices (SUDs)

This project involves retrieval, disinfection, analysis and simulated reuse of SUDs at Walter Reed Army Hospital. The devices include coronary catheters (percutaneous transluminal coronary angioplasty and electrophysiology catheters) and endoscope accessories (biopsy forceps, snares, cannulas, and sphincterotomes). The results have demonstrated a number of model-specific cleaning and disinfection problems, as well as alteration of performance characteristics such as balloon compliance and catheter slipperiness. Studies with generic material test specimens have shown that the effects of disinfection and sterilization on mechanical properties to vary depending on the material. This research is demonstrating that device specific issues of reuse of SUDs must be addressed on a model-by-model basis.

Effects of UV Exposure on Skin

This study is evaluating the utility of novel non-invasive and biomarker methods for testing and standardizing the responses of skin to ultraviolet radiation (UV). The study involves CDRH, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the National Center for Toxicological Research (all components of FDA); the National Cancer Institute;

and Philips Research Laboratories, The Netherlands. The CDRH program performs UV exposures, biopsies, and non-invasive mechanical, ultrasound, and optical measurements on persons with different skin types and racial/ethnic origins. Other Centers participating in the study investigate responses in different animal models. The results of these studies will lead to new approaches to evaluating the safety and efficacy of UV-emitting or UV exposure-modifying FDA-regulated products, including medical UV lamps, sunlamps, drugs, sunscreens and cosmetics.

Endovascular Stent Standards Development

Under the auspices of the American Society for Testing and Materials (ASTM), CDRH and industry are collaborating to develop detailed test procedures for clinically relevant engineering attributes of endovascular stents. Test methods for various parameters are being validated on six different stent designs. This laboratory effort supports a larger collaborative activity with the Health Industry Manufacturers Association (HIMA) and ASTM that could result in expedited clinical trials for endovascular stents. HIMA is collating a database of clinical outcomes from all stent clinical trials and developing the appropriate clinical endpoints for stent designs with certain engineering characteristics. Differences in engineering characteristics, measured by uniform procedures, may help explain the differences in clinical outcomes.

Standards Management

Participation in Standards Organizations

In FY'99 the Center managed the participation of 240 liaison representatives in almost 500 standards development efforts, and 63 staff members in the operation of 13 Specialty Task Groups. These efforts included review and comment on more than 360 standards documents, and recognition of approximately 100 consensus standards for use in CDRH's regulatory programs.

Research Related to Latex Allergies

CDRH has completed development of an ELISA Inhibition Test protocol for measuring natural rubber latex (NRL) proteins, which are responsible for allergy to latex. This method has been shown to be a more sensitive assay for quantifying NRL proteins than those currently in use. The method has been submitted to the American Society for Testing and Materials (ASTM) for consideration by the committees responsible for standards on gloves and condoms. CDRH research also contributed to the development of guidance documents for protein and chemical sensitivities (http://www.fda.gov/cdrh/ode/944.html) and a standard method for protein measurement (ASTM D5712).

Regulatory Compliance

Quality System Inspection Technique (QSIT)

CDRH and FDA field staff worked with the medical device industry to reengineer the process used for Quality System inspections. The new technique significantly reduces the inspection time and increases the effectiveness of the inspection. This will allow the Agency to get closer to meeting its statutory requirements for inspections.

Hazard Analysis Critical Control Points (HACCP)

HACCP uses a systematic methodology to identify critical functions in a product specific manufacturing process. If that process is not controlled, it could lead to defective or unsafe products. Our HACCP reengineering team met with industry personnel to develop the project. Several medical device manufacturers volunteered to implement a HACCP system to study its value.

The Medical Device HACCP Training Workshop made its debut in May 1999. Approximately 500 individuals have thus far received training in the concept of medical device HACCP. The first draft of the Medical Device HACCP Training Manual was made available at these workshops.

A Medical Device HACCP Pilot Study is being drafted and is nearly finished. The study serves two purposes: (1) to detail procedures to be used by FDA to enroll firms in the pilot study; and (2) to conduct "site evaluations." The study will allow FDA and the medical device industry to accrue practical experience with the HACCP system and demonstrate the effectiveness of HACCP.

Re-Use of Single-Use Devices

CDRH participated in organizing and conducting the May 1999 American Association of Medical Instrumentation/FDA Public Conference on the Reuse of Single Use Devices. CDRH evaluated existing policy regarding reuse and developed a proposed FDA strategy paper for increased regulation of reprocessing and reusing single use devices. (This proposed strategy was made public in November 1999; see http://www.fda.gov/cdrh/reuse/index.html .) CDRH responded to numerous inquiries regarding the Agency's reuse policy, including a Citizen's Petition.

FDA/Industry Grass Roots Activities

Customer Satisfaction Survey

In January 1999, a *Federal Register* notice announced a one-year "Pilot Customer Satisfaction Survey: Medical Device Inspection Evaluation (March 1, 1999 – February 28, 2000)." The survey asks those manufacturers who have just had a Quality System/GMP or pre-market inspection to comment on the process – before, during and after the inspection. The questions primarily focus on the three initiatives of the first phase of the grassroots efforts – preannounced inspections, annotated comments on the inspectional observations form, and closure letters.

Warning Letter Pilot Test

CDRH and the field offices implemented the Warning Letter Pilot Test. The pilot allows firms 15 days to respond/correct problems identified during an inspection. Warning Letters are not issued if corrections are adequately addressed. This has a positive impact on a firm's standing within the

medical device industry, while encouraging companies to correct problems quickly.

Anticipating Inspections – Post PMA, PDP, HDE

A *Federal Register* Notice of Availability for Comment was published August 5 announcing guidance entitled "Likelihood of Facilities Inspections When Modifying Devices Subject to PMA Approval." This guidance will help manufacturers determine whether an FDA inspection will occur and more easily implement changes in manufacturing facilities, manufacturing methods or procedures, labeling, design or performance. In some cases, no inspection will be necessary.

Postmarket Programs

Systematic Technology Assessment of Medical Products (STAMP)

Through the STAMP program CDRH shares its knowledge of marketed medical devices with clinicians, consumers and industry. A new committee is chosen for each device selected for STAMP review. The members of the committee, specially chosen for their expertise in the chosen device area, identify the issues related to the device, the public health impact of the device, and the best vehicle for disseminating the information. In the four STAMPs conducted this year, information was gathered through literature searches, consultation with researchers and clinicians, and the bringing together of experts in the specific device area. CDRH disseminated its information through workshops, journal articles, mass mailings, and postings on the CDRH web site. Web sites:

http://www.fda.gov/cdrh/stamp/shuntconf.pdf
http://www.fda.gov/cdrh/consumer/lymedisease.html
http://www.fda.gov/cdrh/ode/wbcw-transcript.pdf

Public Health Notifications

Notifications are the primary means for CDRH to communicate to users of medical device information regarding postmarket safety issues. Two types of notifications are issued by CDRH. The Safety Alert is used for notification when the public health risk is perceived to be in the highest risk category. In 1999, Safety Alerts were issued to health care providers about risks from potential cross-contamination linked to hemodialysis treatment, and potential risks related to use of glass capillary tubes.

The Public Health Advisory is used to communicate information about devices when the risk is perceived to be not as high as that required for a Safety Alert. In 1999, Public Health Advisories notified healthcare providers about reports of explosions and fires in aluminum oxygen regulators, and risks of infections from endoscopes inadequately reprocessed by automatic reprocessing systems. These and other notifications are available at http://www.fda.gov/cdrh/safety.html

Medical Device Adverse Event Reporting (MDR)

FDA receives medical device adverse event reports involving deaths, serious injury, or malfunctions through voluntary and mandatory reporting programs. FDA staff analyze the reports to determine if use of a particular product is resulting in unexpected problems or risks, and to identify trends that can improve risk management and reduce user error. In 1999, over 90,000 voluntary, mandatory and summary reports were received. For more information see http://www.fda.gov/cdrh/mdr.html

Summary Reporting

To reduce the reporting burden to the medical device industry, the Center issues reporting exemptions to manufacturers of various medical device products. These exemptions allow manufacturers to submit reports on specified adverse events in a summary form on a quarterly basis. This program has resulted in a significant decline in the amount of time devoted to processing individual reports while still allowing effective monitoring of the exempted device problems. Forty-five device manufacturers are now participating in the summary reporting program and 52 individual product classification codes are included in the program.

During the past year, CDRH has worked to enhance the current summary reporting program. As a result, the new Alternative Summary Reporting (ASR) program was developed. All participating manufacturers were notified of the changes and their exemption approvals were modified to meet the new requirements. Under ASR, the required summary data elements will be submitted in a line-item format and will correspond directly with the manufacturers' internal complaint files, further reducing the reporting burden. CDRH has also created a new database for the ASR data. It allows for custom trending and analysis by the Center's postmarket surveillance staff. The first group of ASR reports will be entered in January 2000.

Medical Device Reporting Guidance Documents

Two guidance documents were created this year pertaining to MDR reporting. "The MDR Reporting Guidance for Date-Related Problems Including Y2K" may be used by the medical device industry and medical device user facility community to determine when to report medical device events that are computer-related problems associated with the year 2000 (Y2K) and other date-related problems. Web site: http://www.fda.gov/cdrh/postsurv/2299.pdf or http://www.fda.gov/cdrh/postsurv/2299.html

"The Y2K Exemption – E-19999018, MDR Guidance Document", establishes a reporting exemption for firms that receive reports of MDR reportable malfunctions involving a Y2K related problem and decide not to initiate a remedial action. Web site:

http://www.fda.gov/cdrh/postsurv/E1999018.pdf or
http://www.fda.gov/cdrh/postsurv/E1999018.html

Medical Device Surveillance Network (MeDSuN)

FDAMA directed FDA to change the current MDR regulation pertaining to user facilities from a required universal reporting system to a system comprised of a subset of user facilities. A report to Congress explaining the results of the Phase I pilot, future plans from the MeDSuN Phase II pilot, and future plans for the national program can be viewed at http://www.fda.gov/cdrh/postsurv/medsun.html .

Postmarket Surveillance Studies Guidance Documents

To explain the Agency's position to industry regarding certain postmarket surveillance issues, the following two guidance documents were published: "SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols" (http://www.fda.gov/cdrh/modact/smdatran.html) and "Guidance on Criteria and Approaches for Postmarket Surveillance" http://www.fda.gov/cdrh/modact/critappr.pdf .

Timely FDAMA Implementation

Overall Thrust of the Program

"On Track, On Time" is the motto of CDRH's FDAMA implementation team. We are striving to implement FDAMA in a timely and comprehensive manner. During our second year of FDAMA implementation, we have focused on: two reports to

Congress, due November 1999; listening to our stakeholders and evaluating/reassessing what we've already done; and addressing the FDAMA provisions related to dispute resolution and the "least burdensome means to market" provision.

What We've Accomplished

In two years of implementing FDAMA, we have met our statutory deadlines. We have issued 24 guidance documents and 6 final rules to implement the various FDAMA provisions and have implemented programs for recognition of consensus standards and FDAMA third party review (see http://www.fda.gov/cdrh/modact/modern.html). Most recently, two important projects have been reports to Congress and continued interaction with stakeholders. All activities implementing FDAMA were accomplished with no additional appropriated funds.

Reports to Congress, Clinical Trials Database

FDAMA requires two reports to Congress by November 1999. We issued a report on Designing a Medical Device Surveillance Network (MeDSuN) in September (http://www.fda.gov/cdrh/postsurv/medsun.html). We are working on a report to address the feasibility of adding device investigations to a clinical trials database, FDAMA section 113(b). The latter report will include feedback from a public meeting and comments in response to a Federal Register notice.

Interaction with Stakeholders

We have also continued listening to our stakeholders, receiving over 100 suggestions for improvements and changes following Dr. Henney's live video teleconference on April 28, 1999. Information for FDA's stakeholders can be found at http://www.fda.gov/oc/fdama/comm/. We have already applied this feedback to guidance on device tracking, panel procedures and consensus standards.

Guidance on Dispute Resolution and "Least Burdensome Means to Market"

CDRH issued two new draft guidance documents that address issues of significant concern to our stakeholders. One deals with dispute resolution, section 404 of FDAMA (http://www.fda.gov/cdrh/resolvingdisputes/1121.html). The other draft guidance deals with the FDAMA provision on the "least burdensome means to market" for medical devices (http://www.fda.gov/cdrh/ode/1154.html).

Mammography Quality and Radiation Programs

Mammography Quality

General

The goal of the Mammography Quality Standards Act (MQSA), implemented by FDA's Center for Devices and Radiological Health (CDRH), is to enhance the detection of breast disease through high quality mammography services. Under the law, mammography facilities must be certified by the FDA and accredited by a non-profit body; this includes meeting Federally established quality standards and undergoing annual inspections. Final MQSA regulations replaced and enhanced the interim regulations when they became effective on April 28, 1999. CDRH will continue to consult with the National Mammography Quality Assurance Advisory Committee in focusing on issues that are critical to enhancing mammography services, and to streamline MQSA processes to reduce the burden on facilities and make the most use of resources. For detailed information on the items below, visit FDA's Mammography Program Web Site at http://www.fda.gov/cdrh/mammography . The site includes a multi-document search engine that enables users to search by subject matter.

Regulations

The MQSA final regulations became effective April 1999. We also issued the final rule on MQSA Reauthorization (MQSRA), and approved variances for several applicants who demonstrated they were able to comply with MQSA regulations through routes other than those stated in the regulations.

Oversight of MQSA Accreditation Bodies

We approved the state of Texas as the fifth MQSA accreditation body, and made site visits to all accreditation bodies.

Certification

We maintained mammography certificates for approximately 10,000 facilities, and completed the first year of the "States as Certifiers" demonstration program, with approval of Illinois and Iowa as the first two participating states.

Inspection Program and Compliance

We issued two compliance documents on the MQSA final regulations. The first is final, and the second has been made available for public comment. We also began the development of an Inspection Demonstration Project for conducting less frequent inspections of facilities with excellent inspection records. We inspected 98 percent of certified facilities and trained 241 inspectors on the final MQSA regulations. We also notified patients and physicians of several facilities regarding serious concerns about the quality of mammography services at those facilities.

Radiation Outreach Programs

Nationwide Evaluation of X-Ray Trends (NEXT) Surveys

We continued work on the NEXT program, which was established in 1973 in order to estimate the

radiation exposure from specific diagnostic x-ray procedures. NEXT is an annual survey program conducted cooperatively between FDA and the various state and local governments through a coordinating agency known as the Conference of Radiation Control Program Directors. During FY 1999, we submitted for publication the survey on chest and abdomen/lumbosacral spine radiography. In addition, we began analyzing the data from the surveys on upper-gastrointestinal fluoroscopy and pediatric radiography. We also received the dental survey data and drafted the protocol for the computed tomography survey.

X-Ray Computed Tomography

We began developing a handbook of patient tissue doses for multiple types of x-ray computed tomography scanners and examinations.

Outreach

We broadcast a video teleconference for mammography facilities nationwide, in which we explained the final MQSA regulations and their effect on the practice of mammography, and answered questions live and on the air. More than 2,000 viewers across the country participated.

International Activities

Global Harmonization Task Force (GHTF)

Formed in 1992, the GHTF, comprised of government and industry representatives worldwide, is working to build an international consensus on device regulatory policies and practices. The goal is to enhance public health, promote technological innovation, and facilitate international trade. The United States, through the FDA/CDRH, is a major partner, and chaired the 7th Annual Meeting of the Global Harmonization Task Force, held June 27 – July 1, 1999 in Bethesda, Maryland. FDA is committed to full participation in the advancement of the GHTF's mission and initiatives. On January 29, 1999, CDRH posted a web site dedicated to the GHTF, describing GHTF activities and listing meetings. The site is: http://www.ghtf.org .

U.S./EU Mutual Recognition Agreement (MRA)

On December 7, 1998, the Medical Devices Annex to the landmark Mutual Recognition Agreement (MRA) between the United States and the European Union (EU) entered into force. The Medical Devices Annex covers the exchange of quality systems evaluation/inspection reports for all medical devices and product evaluation reviews for selected low to medium risk devices. In June 1999, CDRH posted a web site dedicated to MRA activities, including implementation activities, eligible device lists, MRA meeting minutes, and the list of nominated U.S. and EU Conformity Assessment Bodies (CABs) that are participating in confidence building activities. Under the MRA, both the U.S. and EU may eventually be able to save resources by relying on evaluations of manufacturers and products conducted by the other country. The address for the MRA web site is: http://www.fda.gov/cdrh/mra/index.html

Joint Premarket Review Activities

An offshoot of our involvement in the GHTF is a pilot "partnering" program with Canadian health authorities in which common approaches to conducting premarket evaluation for selected types of devices are being tested as the possible basis for mutually recognized and joint premarket evaluations. A similar program with Japan is underway to test a new universal format for submissions. This universal format would streamline work for companies that market internationally, saving time and resources and allowing needed medical devices to reach patients as quickly as possible. If successful, both programs may reduce the resources being spent on global premarket evaluations of devices and avoid delays in market introduction.

Preparations for Y2K

Planning for Y2K Within the Center

Desktop Computers

Tested all desktop PCs and laptops, identified those that were not compliant, and replaced them with Y2K-compliant units as part of an Agency-wide mass PC buy.

Database Applications

Tested all database applications and performed all necessary modifications and upgrades to bring them into Y2K compliance. These include medical device premarket tracking systems (e.g. 510(k), PMA, and IDE), Medical Device Reporting (MDR) systems, radiological health tracking systems, Registration and Listing systems, and all other major computer applications used in the Center. Also included is the Mammography Program Reporting and Information System (MPRIS), which went through independent verification and validation by contractors.

Network Infrastructure and Facilities

Conducted extensive surveys, modifications, and upgrades of all network infrastructure, security systems, and telecommunications equipment. An independent contractor has validated the Center's network and facilities infrastructure as Y2K-ready.

Day-One Plans

Computer staff will gather on December 31, and by noon on January 1, will have tested all network infrastructure, desktop computers, and database applications for Y2K readiness. This will assure that testing and any necessary trouble-shooting will be completed in time for employees returning the following Monday.

Business Continuity and Contingency plans

Business continuity and contingency plans are being developed which will provide the Center with the operational policies needed to permit business continuity in the event of system failure.

Planning for Y2K Outside the Center

Y2K Clearinghouse

Continued to provide information on the Y2K status of biomedical products through the Federal Y2K Biomedical Equipment Clearinghouse. Manufacturers were requested to provide information on Y2K compliant as well as Y2K non-compliant computerized devices. Data from over 4,200 manufacturers is available via the Clearinghouse at http://www.fda.gov/cdrh/yr2000/year2000.html .

Sample assessments

Conducted focused, on-site assessments of a sample of manufacturers for computer-controlled potentially high risk devices, to help assure that device manufacturers have adequately assessed Y2K vulnerable products and taken appropriate actions to develop any needed corrections. See the final report at http://www.fda.gov/cdrh/yr2000/cdrh/phrds/phrdfinalrpt.pdf .

Manufacturer survey

Surveyed the manufacturers of essential medical and surgical supplies whose availability is critical to patient care. The voluntary survey of 3,070 manufacturers demonstrated that the medical device industry is taking appropriate steps to assure the continued availability of necessary supplies. The full report on the survey is available at http://www.fda.gov/cdrh/yr2000/cdrh/readiness/y2kreadrpt.pdf .

Outreach to healthcare facilities

Communicated with healthcare facilities to urge that they assess the Y2K status of the devices they use, to provide information on the resources available to assist with Y2K preparations, and to explain how to report Y2K-related medical device problems or malfunctions to the FDA.

Internet and telephone access

Expanded the medical device Y2K-related information available on the FDA World Wide Web site and supported expansion of the FDA consumer telephone "hotline" to address Y2K-related inquiries.

Rapid response to Y2K problems

Developed plans and identified staff to rapidly respond to reports of device performance problems or potential supply disruptions due to Y2K problems, using normal regulatory procedures.