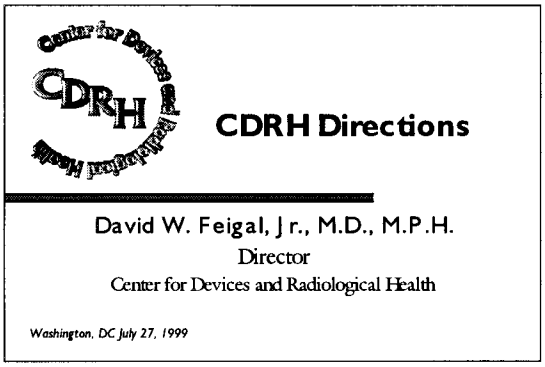

Center for Devices & Radiological Health
CDRH
CDRH Directions
David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health
Washington, DC July 27, 1999

Overview

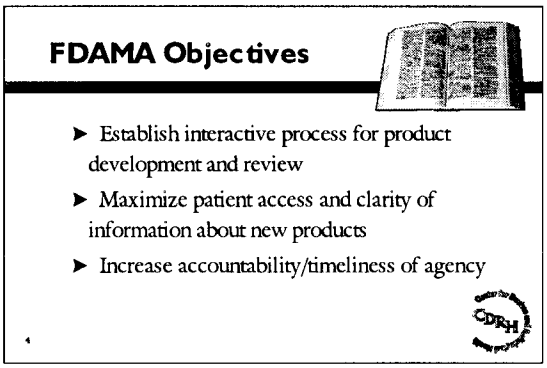
- Dr. Henney's Priorities and CDRH
  - FDA Modernization Act
  - Building a Stronger Science Base
- Reengineering
- Budget and Resources
- Harmonization
- Hot Topics

2

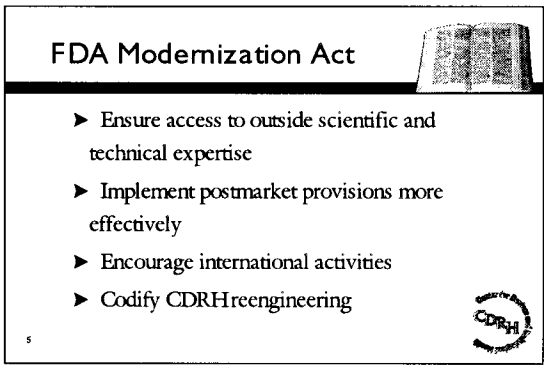
Dr. Henney's Priorities

"My priority as Commissioner will be:

- to implement the FDA Modernization Act; and,
- to strengthen the agency's scientific base to ensure the best science guides the critical decisions that need to be made."



- Dr. Henney has stated that implementation of the FDA modernization act of 1997 is her top priority. Needless to say, that is also a top priority of the center's.
- I think it is worth reiterating very briefly what FDAMA was intended to accomplish: first and foremost, with respect to medical device regulation, the statute was intended to encourage an interactive product development and review process; communication with industry is a primary directive of the new legislation.
- The new law also seeks to maximize patient access to promising therapies and products and to ensure that users and patients have information about products as early as possible.
- The law emphasizes the need for FDA to be timely and to be accountable in its decision-making.
- It encourages access and use of outside scientific and technical expertise.
- It encourages more effective and efficient use of postmarket controls such as tracking, postmarket surveillance studies, and injury reporting.
- And it directs the agency to engage in international activities that promote global harmonization.
- FDAMA also codifies many of the reengineering efforts that CDRH began before the legislation was passed -- e.g. expedited review of PMAs, Class I exemptions, and recognition of standards.



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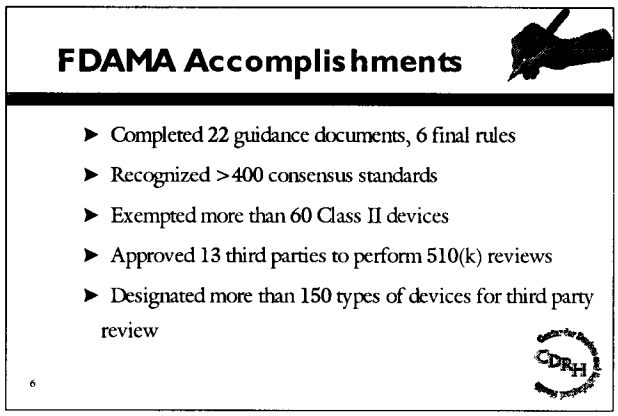
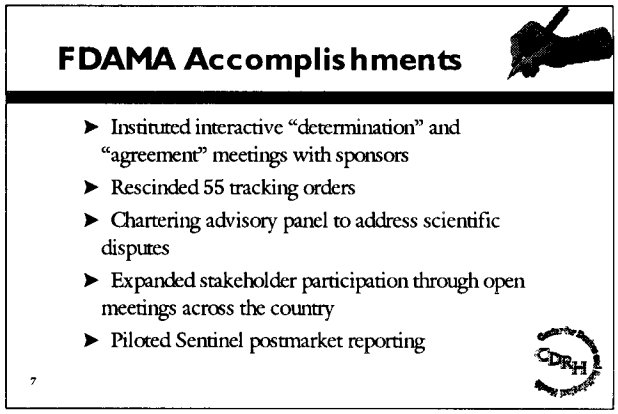


- This list illustrates the center's FDAMA implementation up until now.
- We were very anxious to avoid the kinds of delays in implementation that occurred following the Safe Medical Device Amendments of 1990.
- We succeeded in doing that (and I have to remind you that there were no additional funds appropriated for FDAMA) and I think most of you are probably very familiar with these achievements.
- We put out many guidance documents and final rules (more than many of you could digest).
- We recognized more than 400 consensus standards.
- We exempted more than 60 class II devices from premarket requirements.
- We put the third party review program into place on time, designated 13 third parties to do 510(k) reviews, and made more than 150 types of devices eligible for such review.
- We rescinded 55 tracking orders.
- We've begun chartering an outside panel to address scientific disputes.
- And we've piloted the Sentinel postmarket user reporting system.
- These were all necessary and important achievements and they reflect an enormous investment of center time and resources. But I think it is only fair to expect your question to be, "So what have you done for me lately?"



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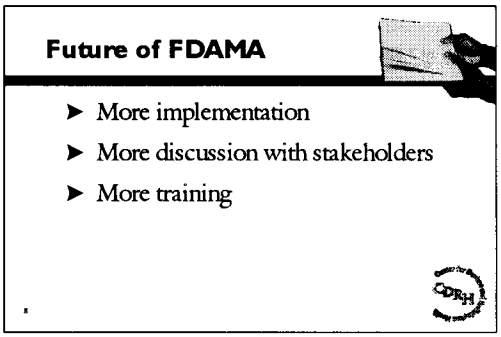


- So, let me try to anawer that.
- The future of FDAMA activities in the center will be more implementation, more discussion with stakeholders, and more training.

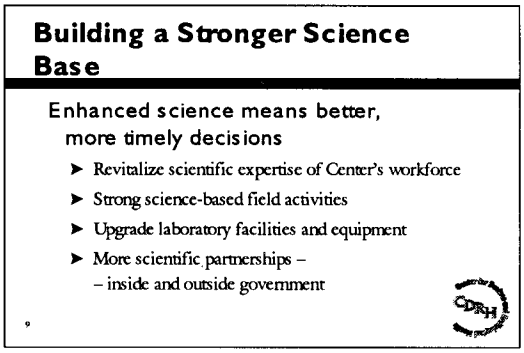
- FDAMA mandated many changes and many activities and it is taking time for the center culture to fully change and adapt. We recognize that there sometimes has been frustration with the pace of implementation at the staff level and we have heard your concerns that there are still reviewers and inspectors who are not comfortable with the collaboration and interaction that is so basic to FDAMA.

- We plan to address those concerns over the next year in a variety of ways.
    - We will be doing additional staff training and trying new formats and tools for that training: interactive computer program training, e.g., is being considered -- along with the possibility of simulations and demonstrations that will give people practice using the new process and approaches.

    - We also plan to review the guidances that we've already put out and see if there are additional refinements that make sense at this point.

    - Along with the rest of FDA, we will be conducting stakeholder meetings to hear from all our customers and, as the new Center Director, Dr. Feigal has personally made it a point to meet with many different groups and ask for input on a variety of issues, including FDAMA

    - The current projects that are consuming our energy are establishing ways to use the dispute resolution advisory panel required by FDAMA; preparing guidance that reviewers and industry will be able to use to interpret the "least burdensome" provision of the law; codifying the changes in the device tracking regulations; and preparing a report to Congress on the Sentinel reporting system, which I'll say a bit more about later.



- Dr. Henney's second priority after FDAMA implementation is building the science base at FDA, but it is hard to imagine how that can happen without resources.

- Dr. Henney's vision is very clear: because FDA stands in judgment of the best science this country has to offer, this judgment should be made by the best, most well-prepared scientists, engineers, and clinicians.

- Some of you have heard me say before that enhancing the science base and the least burdensome provisions of FDAMA should really complement each other.

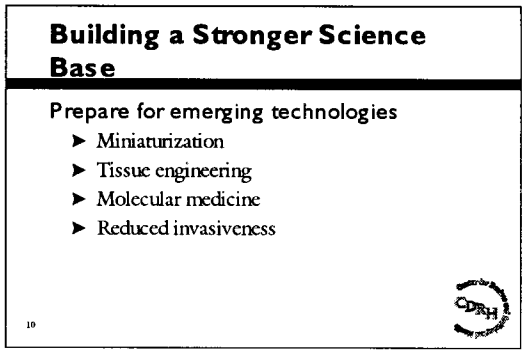
- People who are familiar with the newest technologies and risk assessment tools will ask the right questions, ask for the right amount of information, and ask only as often as necessary. A stronger science base will improve the soundness and timeliness of our decisions and get good products to market more quickly.

- Enhancing the science means many things:

- We need to revitalize the scientific expertise of our workforce, provide continuing education opportunities, and pay close attention to the infrastructure we have to support these people.

- This includes upgrading our laboratory facilities and equipment.

- It also includes continuing and expanding our partnerships with others. FDAMA calls for increased collaboration among FDA, NIH, and other science-based government agencies, but I think we need to expand that to industry and academia as well. We need to be able to participate in conferences, send our staff to training, collaborate with foreign counterparts, and learn about new materials and processes.



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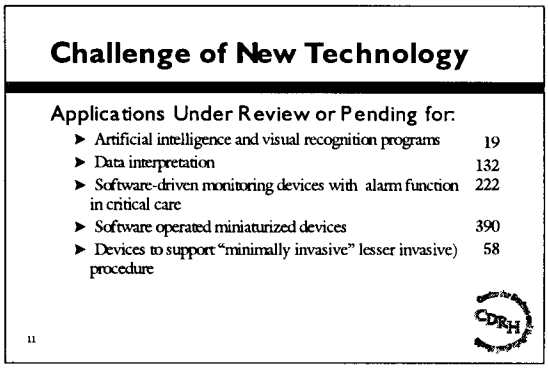


- The challenge of new technology is one of the primary reasons we need to enhance the science base if FDA is not going to be a bottleneck for the cutting edge products that should get to market.

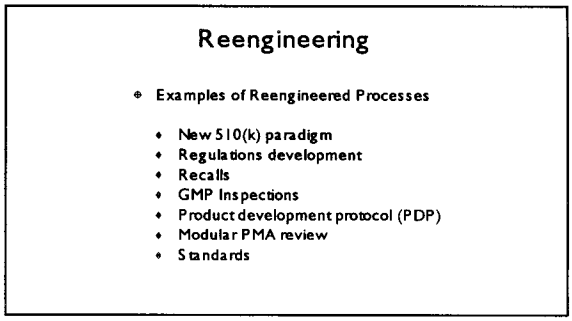
- At last count, there were about 800 device applications in house that depended on new or advanced technology. The slide lists some of the types of devices that have been reviewed or are pending that demonstrate the rapid advances the industry is making:

- Devices that use artificial intelligence and visual recognition programs, such as the latest automated Pap smear readers.

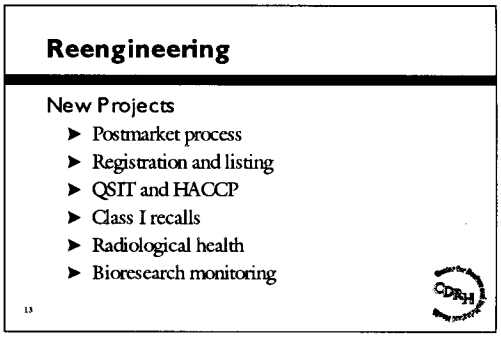
- Devices that interpret data or use software to monitor biologic parameters in critical care situations.

- And increasingly small devices that allow minimally invasive surgical procedures .

- I wanted to share one of the most recent applications with you.



- One of the most important aspects of FDAMA for us is that it codified a lot of what we were already doing in our reengineering efforts:
- As most of you remember, things were not going well in the early 90's. For a variety of reasons, we developed huge backlogs. Industry and Congress were both very critical of us. And morale was low.
- We dug ourselves out of these difficulties with the help of some workload management changes and, in 1994, some new resources of about $13 million, which went mostly to premarket review.
- For the last five years, we basically have had a flat budget but we've been getting a lot more work -- and implementation of FDAMA is just one reason.
- With more work and a flat budget, we needed to reexamine how we did our work and how to refocus resources from lower to higher risk products and activities. We embarked a couple years ago on some business-style reengineering.
- In the premarket notification area, we used a risk-based approach to target our resources. So we exempted most class I's and some II's from 510(k)s, and revamped the process to allow speedier handling of some changes and of applications where manufacturers declare conformance to standards -- the so-called new 510(k) paradigm.
- We improved project management for our regulations development activities, resulting in a better quality product that takes less time to complete.
- We delegated authority for lower-risk recalls to the districts, which had been making the recommendations anyway.
- We made a number of changes to GMP inspections. The field now notifies companies before routine inspections, which has resulted in more organized and efficient inspections. Companies can also make corrections on the spot to some deficiencies we find during the course of the inspection. This results in faster resolution of problems.
- And we revitalized an authority we already had but had not used, the product development protocol, where we and the manufacturer agree on the needed data and the product can go to market when the up-front agreement is fulfilled.
- We now have a process for accepting PMAs as a compilation of modules that together become a complete application. The process utilizes early meetings with industry to identify data needs and resolve issues. So far, we've received about 75 PMA shells. Four have been completed and 3 of them were done in under 180 days from start to finish.
- We have also recognized over 400 national and international standards, and have developed a standards database that can be accessed by all Center staff.



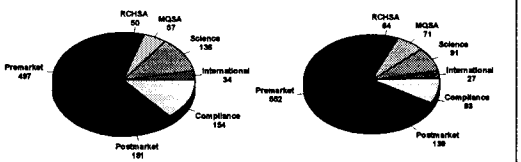
- Our reengineering efforts are continuing in several new areas. This list shows the new teams that are currently operating. The three I wanted to touch on here are postmarket process, registration and listing, and QSIT and HACCP.

- The postmarket process refers to what occurs to the product after it's on the market. We need to do a better job integrating our postmarket experience data, including adverse event data, with our premarket program, and we need to feed information back to manufacturers and users to improve the product and the ability of purchasers and patients to use it safely and effectively.

- We've held a number of meetings with industry and other stakeholders all across the country to discuss the possibility of manufacturers using the Internet to register and list electronically. This would streamline the process and reduce the burden on manufacturers and at the same time provide FDA with a more reliable database.

- QSIT is an acronym for Quality System Inspection Technique and HACCP is Hazard Analysis and Critical Control Points. I'll talk about them a little bit more later on. These are processes we're developing to change the nature of inspections to a quality systems approach. Our goals are to achieve shorter inspections that uncover the more important problems and result in more productive interactions with companies.

CDRH Work Force Distribution



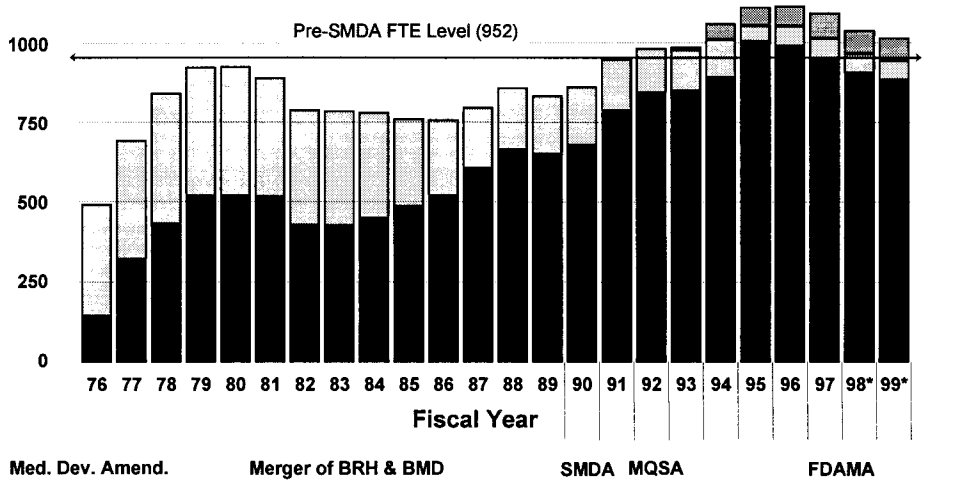
FY95
N=1,109

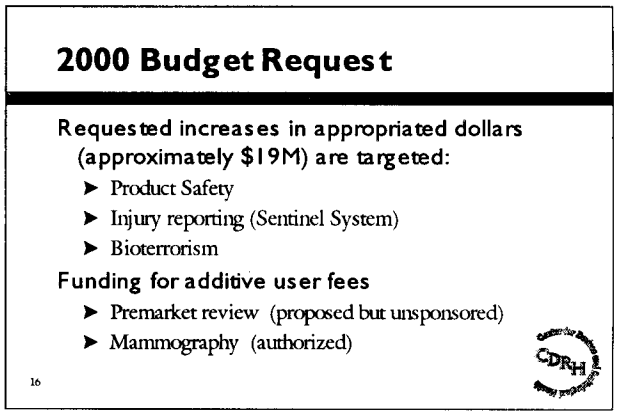
FY98
N=1,037

14

CDRH FTE History

Fiscal Years 1976 - 1999*





- The President's FY2000 budget request for devices and radiological health is for a $27M increase.

- Almost $19M of that is for product safety, primarily for inspections, and most of that money would go straight to state contracts. This requested increase won't get us to inspections once every two years, but it would reverse the downward trend for class II and III devices.

- That requested increase includes $3.3M for injury reporting, most of which would go to the second phase of the pilot Sentinel reporting system.

- The budget also includes a half million dollars for bioterrorism to hire experts for premarket review staff.

- $.4M is also included for current services in user fees for mammography.

- The latest House action on the Y2K budget cut $20M from FDA. The Senate hasn't taken any final action.

- The budget outlook is changing by the moment so I don't know where we'll end up. But the gap between what we need to do our job and the funding we have remains significant.

- When I talk about user fees in a little while I'll try to explain why I think that is one approach that has promise for future funding.

Resources Are Shrinking

- Flat line budgets have meant actual decrease in funds available for program.
- CDRH down 113 FTEs since FY 1996; includes 45 positions cut in last fiscal year.
- FDAMA added new responsibilities without funding.
- International activities are costly.

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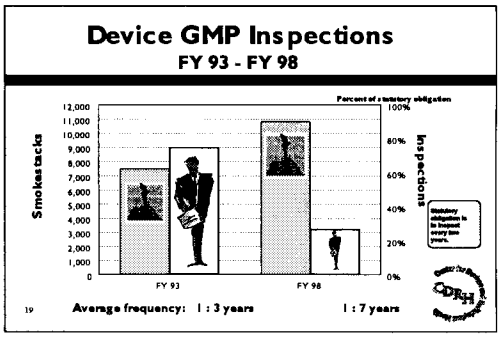
Resources Are Shrinking

- Workload complexity is increasing.
- Review timeframes are still too long (e.g., PMAs – 12.4 months total elapsed time).
- Administration's FY 2000 budget does not request additional premarket resources.



- Enhancing the science base isn't something that applies only to the premarket activities of FDA.

- Providing training to our field staff, and in particular to the inspectors that visit facilities, is the kind of investment in science that should result in more efficient and more useful interactions between FDA and industry.

- Like reviewers, field Investigators who understand the materials and technology of the products being manufactured are more likely to ask the right questions, understand what they observe, and know what needs follow up.

- As I mentioned, there is a $27M increase request in the President's budget for CDRH. This slide of the "shrinking inspector" explains why most of this has been targeted for product safety, and, primarily, for inspections.

- The law requires us to do biennial inspections. In 1993 we were almost meeting that, at about 1 inspection per 3 years. But we're now down to 1 every 7 years on average.

- A weak inspection program is bad for FDA, for consumers and for industry. When we don't inspect, there is a greater likelihood that there will be problems.

- In addition, if the inspection program is not credible and robust, confidence in the reengineering and FDAMA initiatives are bound to diminish because many of those new approaches rely on certification, standards, and third parties. If FDA does not inspect, no one can be sure these new approaches are working.

- As I mentioned earlier, the current request for 2000 won't get us to 100% of our statutory obligation but it will reverse the downward trend for class II's and III's. But we still would not be doing any routine class I inspections, which remains a problem because so many products are now exempt from premarket review of any kind.

- But just increasing the number of routine surveillance inspections isn't enough.

- We need to change how we do inspections: To make them more useful to manufacturers and consumers and to concentrate on the serious problems and not on the trivial ones.

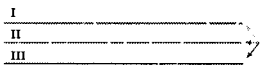
Work Load and Resources

Staffing Level

I: Nearly all "on time"

II: Average "on time" (i.e., half over/half under)

III: Backlogs



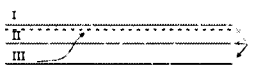
510K 55 hours
PMA 2000 hours

20

Work Load and Resources

Options:

- Increase Productivity
  - Improve Skills (Science Base)
  - Retain Experienced Reviewers
  - Develop a Reviewer "Reserve"



510K ? hours
PMA ? hours

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Work Load and Resources

Options:

- ➤ Re-Engineer the Process
  - Modular PMA
  - Real Time Decisions
  - Special 510K
  - Abbreviated 510K
  - Standards Development

510K ? hours
PMA ? hours

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510(k)s - Alternatives

	Applications Received (4-98 to 7-99)	Review Complete	Average Review Time
Abbreviated	92	69	87
Special	373	333	27
Traditional	5552	5834	110

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Reengineering--

No Replacement for Funds

- Reengineering is bringing diminishing returns.
- FDAMA premarket provisions cannot be fully implemented without funding
- Product review program cannot meet all the demands placed on it; review times may slip
- CDRH cannot shift more resources from other programs without jeopardizing public health

Work Load and Resources

Options:

- "Off Load"
  - 3rd Party Review
  - Down Classify / Exempt
- "Load Balancing"
  - Lengthen Review times

I
II
III

510K ? hours
PMA ? hours

25

510(k)s - Third party review

- 154 device types eligible
  - mostly class II
- same device types =1200 510(k)s / yr
- only 20 510(k)s submitted to 3rd parties so far this fiscal year

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Resource Strategy
Review Times Based on Priority

Higher Priority

- ➤ High Public Health Impact
  - High risk
  - Novel benefit
- ➤ Encourage Use of Re-engineered Processes
  - 510K (Abbreviated / Special)
  - Standards
  - Modular PMA

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Resource Strategy
Review Times Based on Priority

Lower Priority

- Public Health
  - Low impact
  - "Me too"
    - For example, In CDER the second drug in a class has twice the review time of the first one (standard and priority review)
- Applications eligible for re-engineered processes that didn't use them

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Global Harmonization

7th meeting on J[illegible] 27-July[illegible] 1999
Hosted b[illegible]e U.S.

Http://www.fda.gov/cdrh/harmmain.html

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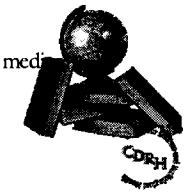
Benefits of Harmonization

Greater uniformity and standardization in regulation of devices by different nations

- Facilitate international trade
- Help expand global markets
- Broaden access to important medi technologies
- Inter-Regualtory Agency information sharing



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Hot topics

- Dispute Resolution
- Least Burdensome
- Re-Use
- Home Brew
- Tissue / Bioengineered Products
- Internet Promotions
- Point of Care Devices

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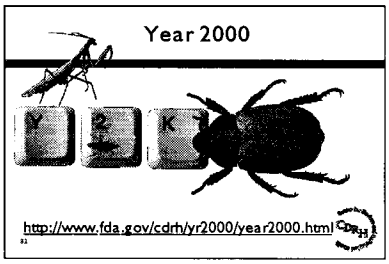

- Speaking of the year 2000, I, for one, am going to be very happy when January 1, comes and goes.

- Many people have expressed concern about what will happen to medical devices that are date dependent when the new millennium arrives.

- In response to those concerns and at the direction of the White House, OMB, HHS, and Congress, FDA has become something of a focal point for Y2K readiness. By this time, you all know we are running the government's Y2K web site on the status of biomedical equipment.

- We asked all manufacturers to list information about their equipment on the site -- whether their devices are date dependent; if so, do they have a problem-- if they have a problem, how can it be fixed? The FDA web site also provides links to manufacturers' individual web sites. Despite many letters from us, some companies have still not submitted information to the Website.

- Partly because the industry got off to a sluggish start, partly because we did not communicate our activities to a wide enough audience, and partly because there is a certain amount of hysteria out there about the new year, FDA has found itself in the position of having to do more and more to assure people that there are unlikely to be many serious problems with medical devices because of Y2K.

- FDA has recently identified and will list on the web, perhaps as soon as today, around 80 types of devices that are potentially high risk devices (we call them PHRDS) that could cause serious problems if they fail. Examples include: fetal cardiac monitors, emergency ventilators, and radiation therapy planning systems. The agency has identified about 650 manufacturers who make these types of devices.