

The Food and Drug Administration's Response to the Y2K Challenge

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Overview of FDA's Y2K Efforts

- ◆ FDA's mission critical systems are/will be ready
- ◆ Monitoring regulated industry progress
 - Computerized products (devices)
 - Impact on production/product availability

FDA's responsibilities related to medical devices

- ◆ Regulations primarily apply to device manufacturers
- ◆ Limited controls on healthcare facilities
 - User facility reporting of adverse events
 - Mammography Quality Standards Act
 - Clinical investigations of new products

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CDRH/FDA's principal activities related to medical devices

- ◆ Premarket Review of New Products
- ◆ Manufacturing Oversight - Quality System Regs.
- ◆ Postmarket Surveillance and Medical Device Reporting
- ◆ Public Health Activities

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Device regulations are in Title 21 of the Code of Federal Regulations

- ◆ According to the Federal Food, Drug, and Cosmetic Act, a "device" is: *an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body and which does not achieve its primary intended purposes through chemical action and which is not dependent upon being metabolized for ... its primary intended purposes.*

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Product Availability ?

- ◆ Interactions with firms and industry associations
- ◆ "Readiness Surveys" of manufacturers
 - Pharmaceuticals
 - Biologics
 - Essential medical/surgical supplies

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Results of Manufacturer Readiness Surveys

- ◆ Vast majority of firms report plans and preparations to be ready
- ◆ Validation of survey responses
 - Telephone and on-site audits of survey responses
- ◆ Focus on "high priority" firms
- ◆ FDA follow up via inspections possible

Y2K Impact on Medical Devices

- ◆ Majority of Y2K problems are minor - display or printing of date records
- ◆ Small number of significant risks - healthcare facilities must be vigilant
- ◆ Web Site - Federal Y2K Biomedical Equipment Clearinghouse
- ◆ Extensive use of FDA Web Site - <http://www.fda.gov>

Y2K Impact on Medical Devices

- ◆ Identification of types of computer-controlled, potentially high-risk devices
- ◆ Assessment of a sample of manufacturers via a contractor - review of processes and activities
- ◆ Careful review of Y2K status of high-risk devices

FDA authority for problem products

FDA can take action to require a manufacturer to recall a device that presents:

"an unreasonable risk of substantial harm to the public health."

What does this mean?

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The Biomedical Equipment Database

- ◆ FDA operated world wide web site
- ◆ Data provided by manufacturers
- ◆ Voluntary submission of data
- ◆ "Certification" by manufacturers
- ◆ Continually updated
- ◆ Searchable by manufacturer & model
- ◆ Corporate history information
- ◆ "Downloadable"

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The Biomedical Equipment Database

- ◆ Manufacturers requested to improve data in letter to manufacturers on March 3, 1999
 - Generic product description - FDA Classification Name
 - Description of impact on function
- ◆ Expansion to include information on "compliant" products. Letter to manufacturers on March 29, 1999

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Original FDA product database content

- ◆ Manufacturer lists products which ARE impacted (non-compliant)
- ◆ Manufacturer certifies all products, both current and past production are compliant
- ◆ Manufacturer certifies that none of their products use dates
- ◆ Manufacturer provides a WWW link to their web site where requested information is provided

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Status of database as of September 13, 1999

- ◆ Total manufacturers reporting - 4,268
- ◆ Manuf. reporting non-compliant products - 693
345 - database; 348 - URL
- ◆ Manuf. reporting all products compliant - 896
- ◆ Manuf. reporting no products use dates - 2,600
- ◆ Manuf. reporting World Wide Web link - 427
- ◆ Individual problem devices in database - 1,019

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FDA definition of Year 2000 compliance

- ◆ Contained in January 21, 1998 letter to manufacturers
- ◆ Based on definition in the Federal Acquisition Regulations
- ◆ Comprehensive product information
- ◆ "Non-compliant" does not mean a "risk to public health"

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FDA Definition of Year 2000 compliance

- ◆ For the purpose of the database, Year 2000 compliant means, with respect to medical devices and scientific laboratory equipment, that: *the product accurately processes and stores date/time data (including, but not limited to, calculating, comparing, displaying, recording and sequencing operations involving date/time data) during, from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including correct processing of leap year data.*

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What does the product database show us?

- ◆ Manufacturers of the majority of vulnerable products have reported
- ◆ Most non-compliant products involve date display or date recording - "date stamping"
- ◆ Limited number of products with significant "operational" problems
- ◆ PC-based products have "PC" type problems
- ◆ Manufacturers are providing solutions - a variety of approaches

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What are manufacturers responsibilities under the FD&C Act?

- ◆ Market safe and effective devices
- ◆ Comply with Quality System Regulations
 - Investigate and correct product deviations
 - Assess risks associated with deviations and take necessary action, notify customers/users as a minimum
 - Apply corrective action when appropriate

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What are manufacturers responsibilities under the FD&C Act?

- ◆ Report problems with device
 - **Medical device reporting by manufacturers and user facilities**
 - **Reports of corrections and removals to address a risk to public health**

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FDA's role regarding "recalls" related to Year 2000

- ◆ FDA can require recall of devices which present an unreasonable risk of substantial harm to the public health
- ◆ FDA will monitor reports of Y2K problems with emphasis on devices that could present significant risk to patients, and investigate and take action where warranted

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Pharmaceuticals and Biological Products - Done to date?

- ◆ Y2K Issues with Drugs and Biologicals - more likely to involve production, supply and distribution chain
- ◆ Working with Industry
 - Blood product industry - close contact
 - PhRMA /Bio Conference in February, 1999
 - Federal Healthcare Sector Working Group
 - Pharmaceutical Acquisition Working Group
- ◆ Discussions/letters to industry re Y2K

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Pharmaceuticals and Biologicals What does FDA plan to do?

- ◆ Collect information about manufacturer readiness
- ◆ Provide information about firm readiness via the FDA Web Site???
- ◆ Target any problems identified
- ◆ Inform consumers and healthcare facilities of the facts as they are developed

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Healthcare facility issues

- ◆ Inventory and assess (triage?)
- ◆ Obtain information on device status
- ◆ Test devices for Y2K compliance?
 - A legal question for each facility
 - Is greater concern needed for Y2K than for the original design?
 - U.S. regulatory structure relies on the manufacturer.
 - Test as a last resort?

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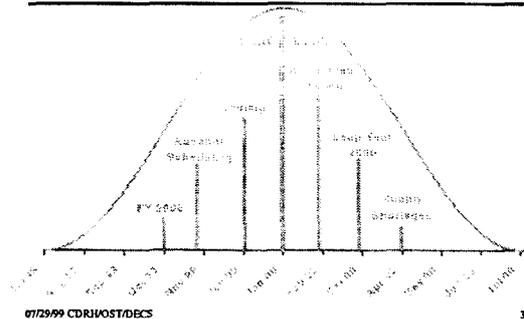
Healthcare facility issues

- ◆ Check interconnected or networked devices
- ◆ Check device-information system connections
- ◆ Plan for or develop "work arounds", upgrades or replacements
- ◆ Develop contingency plans - use resources available on the Web
- ◆ Reporting Y2K-related problems - recent guidance

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Y2K Failure Timing



"Outreach" Activities

- ◆ Messages for industry, healthcare community and consumers
- ◆ FTC and FDA Y2K "Hotlines"
 - FDA at 1-800-INFO FDA
- ◆ Developing messages on "supply availability" based on survey results

FDA product database location

www.fda.gov

Select the Year 2000 item

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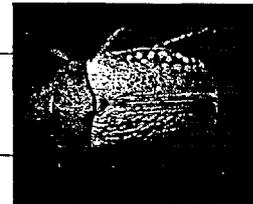
Year 2000



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