

February 22, 2000

**Notice to Users and Manufacturers of Medical Devices
Regarding Possible Leap Year Date-Related Problems with Medical Devices**

Based on worldwide experience, FDA is not aware of any deaths or serious injuries resulting from the Y2K problem and medical devices during the rollover into the Year 2000. Every facet of the healthcare sector contributed to this outstanding outcome.

With the approach of February 29, you should be prepared for the possibility of date-related problems associated with the leap year rollover. Because date-related problems could occur on or after February 29, 2000, we remind you to review your contingency plans and heighten your level of vigilance for possible problems during this time. You can check the Y2K (including leap year) status of computer-controlled devices by consulting FDA's Federal Y2K Biomedical Equipment Clearinghouse (Y2K Clearinghouse) at www.fda.gov/cdrh/yr2000/year2000.html. In addition, the Rx2000 Solutions Institute lists products with reported leap year problems on their web site at www.rx2000.org.

Reporting Adverse Events

Despite careful preparations, unexpected date-related problems could occur on or after February 29, 2000. If you become aware of a medical device Y2K problem that appears to have serious implications for patient safety, please report it immediately to FDA at our Emergency Operations Center. The FDA Emergency Operations Center may be reached at 301-443-1240 or via the FDA information hotline at 1-888-INFO-FDA (1-888-463-6332). For other reportable events, you should report to FDA's MedWatch program as follows:

Mandatory Reports

For any device-related death or serious injury, user facilities are required to report deaths to both FDA and the device manufacturer and serious injuries to the manufacturer only. Manufacturers are required to report to the FDA deaths, serious injuries, and malfunctions that could cause death or serious injury if they recurred. Please report these problems through procedures established by your facility and be sure to identify the report as a Y2K problem, using the following special codes on the FDA Form 3500A, in addition to other appropriate codes:

MedWatch Device Problem Codes, Block F10

2581 - Date-related problem, Y2K

2582 - Date-related problem, not Y2K

MedWatch Conclusion Codes, Block H6

90 - Date-related Problem, Y2K

91 - Date-related Problem, not Y2K

Voluntary Reports

We recommend that you report any date-related problem that did not cause death or serious injury and would not if it recurred but did cause unexpected performance of the device. This would include device malfunctions that could cause death or serious injury if the problem recurred. Again, please identify your report as a Y2K problem. We also encourage you to report any contradiction between your observation of device performance and the performance described by the manufacturer. Voluntary reports may be submitted as follows:

By telephone, to 1-800-FDA-1088

By FAX, send Form 3500 to 1-800-FDA-0178

By mail, send Form 3500 to:

MedWatch

Food and Drug Administration, HF-2

5600 Fishers Lane

Rockville, MD 20857-9787

Electronically at: <http://www.fda.gov/medwatch/index.html>

Status of Federal Y2K Biomedical Equipment Clearinghouse

The Y2K Clearinghouse is a database established to provide healthcare facilities and device users with information on the Y2K compliance status of biomedical equipment. The Clearinghouse contains information or manufacturer web-site links for Y2K non-compliant products, and information on specific product models that are Y2K compliant. After February 29, 2000, we will continue to make the Y2K Clearinghouse available on the World Wide Web; however, we will no longer update the information contained there. The existing links to manufacturer's web sites, which have been provided to FDA, will continue to be listed, but some device manufacturers may in the future remove Y2K product status information from their linked web sites. If Y2K information for a specific product is not available through the Y2K Clearinghouse, users should contact the device manufacturer directly.

Sincerely yours,

David W. Feigal, Jr., MD, MPH

Director

Center for Devices and Radiological Health