

December 10, 1999

Dear Medical Device Manufacturer:

I'm writing to thank you and others in the medical device industry for your excellent cooperation in helping us assess the Y2K readiness of the industry and its products. By responding readily to our requests, you have provided the healthcare community with essential information needed to assure continued delivery of health care and patient safety in the year 2000. I'm pleased to enclose a brief summary of recent Y2K activities, which were made possible through your participation and contributions (Attachment 1). These activities include the Y2K Clearinghouse, the Readiness Survey, and the Evaluation of Computer-Controlled Potentially High-Risk Medical Devices. Each of these activities has provided device users essential Y2K information regarding device status and availability.

Evidence indicates that the industry as a whole has done a good job in providing device users with appropriate Y2K status information and making device upgrades available when necessary, and that critical products will remain available after January 1. **As that date approaches, I want to alert you to two important issues that may affect you in the coming year.**

Distribution of Medical Devices after January 1, 2000

Enclosed with this letter (Attachment 2) is a brief description of the current legal requirements that govern continued marketing of medical devices that are not fully Y2K compliant under the definition used by FDA. **If you are considering continued marketing of any Y2K non-compliant device, please review this attachment carefully.**

Reporting Y2K Problems to FDA

Despite careful preparation, unexpected date-related problems could occur after January 1, 2000. If you become aware of a Y2K problem that appears to have serious implications for patient safety and for which immediate notification or alert of other users may be appropriate, **we encourage you to report this information to the FDA Emergency Operations Center at 301-443-1240.** (This action would be taken in addition to meeting the normal adverse event reporting requirements.) A brief description of how to submit such reports is enclosed (Attachment 3).

Thank you again for your cooperation. I know you share our concern and our commitment to assure the safe delivery of patient care as we approach the year 2000.

Sincerely yours,

David W. Feigal, Jr. M.D., M.P.H.
Director,
Center for Devices and Radiological Health

Enclosures: Y2K Activities Regarding Biomedical Equipment
Distribution of Medical Devices after January 1, 2000
Reporting Y2K Problems to FDA

Attachment 1 - Y2K Activities Regarding Biomedical Equipment

Federal Y2K Biomedical Equipment Clearinghouse

More than 4,300 manufacturers responded to our request for information on the Y2K status of their products allowing us to develop the Federal Year 2000 Biomedical Equipment Clearinghouse. The Clearinghouse has enabled device users to obtain Y2K status information for products and to plan any necessary equipment remediation that may be required. Further information regarding the Y2K Clearinghouse may be obtained from the CDRH web site at <http://www.fda.gov/cdrh/yr2000/year2000.html>

Y2K Readiness Survey of Manufacturers of Essential Medical Supplies

In order to assure the healthcare community and the public that an adequate supply of essential medical supplies, including consumable devices, will be available as we move into the year 2000, more than 2,100 manufacturers of these supplies responded to the Y2K Readiness Survey. This voluntary survey of manufacturers' preparations was intended to assure that business and manufacturing operations would not be disrupted by Y2K problems. Manufacturers provided information regarding actions taken to prepare internal systems for the Year 2000, contingency plans, dependency on foreign suppliers, and plans for increased production that may be required to meet increased demands.

We are pleased that the responses to this survey and the cooperation received in the validation of this survey indicate that the vast majority of those manufacturers responding are taking preparations for the Year 2000 very seriously. This effort provides the healthcare community with a high level of confidence that there will not be significant interruptions in the availability of essential medical supplies. Further information regarding the Y2K Readiness Survey may be obtained from the CDRH web site at <http://www.fda.gov/cdrh/yr2000/cdrh/readiness.html>.

Evaluation of Computer-Controlled Potentially High-Risk Medical Devices

The FDA also commends the 80 medical device manufacturers of computer-controlled potentially high-risk devices that voluntarily participated in an evaluation of their processes and procedures used to assess the Y2K status of their devices. Further, if manufacturers identified date-related problems, the procedures used to design, develop, and test upgrades and modifications to correct these problems were evaluated. Lastly, we also evaluated actions taken by manufacturers to communicate relevant information to their customers.

These assessments, conducted by a contractor, demonstrate that healthcare facilities and the public can have confidence that medical devices and upgrades to devices are designed, tested, and manufactured with appropriate care and attention to assure that they are safe and effective. Should you desire further information regarding the Evaluation of Computer-controlled Potentially High-Risk Medical Devices, check the CDRH web site at <http://www.fda.gov/cdrh/yr2000/cdrh/phrds/phrds.html>

Attachment 2 - Distribution of Medical Devices after January 1, 2000

As you know, "adequate directions for use " must accompany all medical devices marketed in the U.S. and the device labeling must not be "false or misleading in respect to device performance." This means that a device with a Y2K problem that is not clearly disclosed in the labeling and described in the directions for use would be in violation of these requirements. In addition, if a device has a Y2K problem that presents a risk of injury or is ineffective, then the manufacturer must correct the problem to remove this risk or restore the effectiveness of the device. In doing so, the manufacturer would use existing regulations and guidance to decide whether the change to the device or its labeling requires a new premarket submission. For a Y2K correction that raises new issues of safety or effectiveness, failure to submit a new premarket submission will render the device adulterated and misbranded and subject to regulatory action. In addition, failure to make a correction when the Y2K problem presents a risk could result in rescission or withdrawal by FDA of the approval to market the device.

If a device has a non-significant Y2K date problem (i.e., the non-compliant performance has no impact on safety and effectiveness), then the manufacturer may take one of several actions in order to continue marketing the device. The manufacturer must:

- (1) change the product to correct the problem; or
- (2) change the product labeling to prominently disclose the existence of the Y2K problem; and provide modified user instructions to avert any adverse effect of the device's use.

The second action would permit a manufacturer to continue to market a device with a non-significant Y2K problem. Manufacturers electing either course of action must do so in accordance with FDA's Quality System Regulation, which requires appropriate design controls, risk analysis, documentation of decisions regarding potential risks, and premarket submissions for any changes that could impact safety and effectiveness.

Although we anticipate that most manufacturers will elect to market fully Y2K-compliant devices, those manufacturers that disclose the non-significant problem and provide appropriate user instructions could continue to market a technically Y2K non-compliant device. This will permit the continued marketing of devices that are safe for use according to instructions, although not fully compliant with the strict definition of Y2K compliance used by FDA.

The Quality System Regulation places several requirements on the manufacture and design of medical devices, including a continuing requirement of adequate corrective and preventive action to address problems with devices. In the Y2K context for significant problems, the types of corrective and preventive action that would be adequate vary depending on factors such as the type of device and the importance of the date-related function. Depending upon the risk posed by the device, adequate actions could range from notification of device purchasers or users to recall or replacement of the device. Failure to take adequate corrective and preventive action will render the device adulterated and subject to regulatory action.

Attachment 3 - Reporting Y2K Problems to FDA

Because of the unique nature of the Y2K problem and the possibility that unexpected date-related problems may arise, if you become aware of a Y2K problem that appears to have serious implications for patient safety and for which immediate notification or alert of other users may be appropriate, we encourage you to report this information to the FDA Emergency Operations Center at 301-443-1240. This action would be taken in addition to meeting the normal adverse event reporting requirements.

As we stated in the April 16, 1999 document entitled "MDR Reporting Guidance for Date-Related Problems Including Y2K" (<http://www.fda.gov/cdrh/postsurv/2299.html>), you must submit a report when you become aware of information that reasonably suggests a device may have caused or contributed to a death or serious injury. In addition, you must submit a report when you become aware of information that reasonably suggests that a device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These requirements apply whether or not the event was a result of a Y2K failure.

FDA has established specific codes to report Y2K problems. The following codes should be used in addition to other appropriate codes in blocks F10 and H6 respectively of the FDA form 3500A (MedWatch form).

Device Problem Codes: (Block F10)

2581 - Year 2000-related problem

2582-Date-related problem, not Y2K

Conclusion Codes: (Block H6)

90-Year 2000-related Problem

91-Date-related problem, not Y2K