

March 3, 1999

Request for Information Regarding Year 2000 Status for Non-Compliant Products

Dear Biomedical Equipment Manufacturer:

In a previous letter, dated January 13, 1999, I advised you of FDA's plans to expand the product information maintained on the FDA-operated Federal Y2K Biomedical Equipment Clearinghouse and asked for your continuing cooperation in this effort. Comments from many biomedical equipment users, as well as our own review, indicated that much of the information on our web site is not sufficiently complete or otherwise informative to adequately assist facilities in assessing the impact of non-compliant products. We are, therefore, requesting that you carefully review the Y2K product status information that you have already provided, or that you intend to submit, and where necessary, provide more specific information. This should include clear identification of non-compliant products and more detailed descriptions of how uncorrected date problems may affect the operation of those products. Please direct your description to equipment managers and biomedical engineers who, in most cases, have the responsibility to advise their facilities on what to do to remain efficiently operational. These individuals tell us they need to know explicitly how each piece of equipment will perform into the year 2000.

This request is a special year 2000 data gathering request made pursuant to the Year 2000 Information and Readiness Disclosure Act. By providing information in response to this request, you agree to allow FDA to use the information you provide to update the Federal Y2K Biomedical Equipment Clearinghouse database.

To assist you in this important effort, we have included the following enclosures that describe the type of information and level of detail we are seeking:

1. An Instruction Sheet that includes: (1) the definition of "Year 2000 Compliance", (2) a description of the level of detail needed to adequately identify the type of product and date-related problem, and (3) information relating to corporate history to assist database users in locating information on products no longer sold by their original manufacturer.
2. An Additional Information Request Form for both manufacturer and Y2K contact information and Y2K product status information.
3. A Product Problem Form for Y2K non-compliant products. If you have non-compliant products identified on the FDA web site, we have enclosed, on this form, the information you provided regarding those products for review and possible revision. If, instead, you have provided a link to another web site, please ensure that the data provided at that web site supplies the detailed information described in the Instruction Sheet.
4. A Product History Form for information related to mergers, acquisitions, or divestments of products or product lines.

Please return all of the attached forms for non-compliant products whose Y2K status information requires revision by mail to the Y2K Coordinator at the address provided on the Instruction Sheet. The Y2K Clearinghouse, copies of forms, and information regarding submissions can be found on the FDA web site at the URL <http://www.fda.gov> by selecting "Year 2000".

I also want to remind you of your obligation to report to FDA certain correction or removal actions that meet the threshold for reporting. If, on or after May 18, 1998, your firm makes a decision to initiate a device correction or removal to address or remedy a potential risk to health posed by a Y2K problem, then your firm must report that correction or removal within 10 working days of the date of that decision to take action (ref.: 21 CFR 806). Note that a Y2K correction or removal will not be classified as a recall if it is fully completed, for all devices in commercial distribution, before the date of the Y2K device failure. Also note that reporting information to the Y2K Clearinghouse or posting information on your firm's web site is not a substitute for this regulatory reporting requirement.

In the coming weeks, you will receive another letter detailing additional product status information we request that you submit for all biomedical equipment that is Year 2000 compliant. Your prompt attention to all of these requests will assure the usefulness of the Y2K Clearinghouse as a resource to biomedical equipment users who require this information for the safe delivery of services and patient care as we move into the year 2000.

Lastly, I want to thank those who responded to our request last year for product information, either by identifying products with Year 2000 compliance problems directly to the Y2K Clearinghouse, or by supplying a URL address where that information could be found. For those of you who have not yet responded, I again remind you of the importance of having this information readily available to biomedical equipment users and, therefore, strongly urge you to work with us on this project.

Sincerely yours,

D. Bruce Burlington, M.D.
Director,
Center for Devices and Radiological Health

Enclosures: Instruction Sheet
Forms for Information Reporting
List of Product Classification Names