

Survey of Biomedical Equipment Manufacturers for Year 2000 Compliant Products

A. Justification

1. Need for Information

Section 705(b) (attachment 1) of the Food Drug and Cosmetic Act (21 U.S.C. 375(b) states that the Secretary may...cause to be disseminated information regarding...devices...in situations involving in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Emergency clearance is requested for the collection of information from manufacturers of biomedical equipment regarding the manufacturer name, type of product and specific model identification information for products which have been identified by their manufacturer as being Year 2000 compliant. Emergency clearance is requested because the proposed information collection is required as soon as possible (by the second quarter of 1999) to allow healthcare facilities and others to assess their vulnerability to Year 2000 problems and to take corrective actions, if necessary, well in advance of January 1, 2000. The existence of a Year 2000 date problem in biomedical equipment could pose potentially serious health and safety consequences. It is vital that there be no Year 2000 failures of biomedical equipment.

Background

In December 1997, the Deputy Secretary of the Department of Health and Human Services, on behalf of the government-wide Biomedical Equipment Subgroup of the CIO Council's Subcommittee on the Year 2000, requested emergency approval from the Office of Management and Budget to survey manufacturers of biomedical equipment about the Year 2000 compliance of their products and to develop a World Wide Web based database on products that are known to be Year 2000 non-compliant.

The Biomedical Equipment Subgroup included representatives from the Department of Health and Human Services, the Department of Defense, the Department of Veterans Affairs, the Department of Agriculture, the Department of Justice, the Nuclear Regulatory Commission, and the Office of Management and Budget. The information collection request was approved and during 1998, FDA has received data from over 3,600 manufacturers regarding products for inclusion in the database.

FDA established the database on behalf of the Federal government and continues to operate it. In August 1998 the Department of Health and Human Services and the Department of Veterans Affairs established a Collaborative Agreement which resulted in the Year 2000 product status data collected by the Department of Veterans Affairs from equipment manufacturers being added to the database and the database being identified as the Federal Y2K Biomedical Equipment Clearinghouse (Y2K Clearinghouse). Data collected by components of the Department of Defense regarding biomedical equipment are currently being added to the database. The Y2K Clearinghouse, begun in January 1998, includes a web-based database of biomedical equipment with known Year 2000 problems. Currently in that database, 353 manufacturers describe 784 products with date

problems.

FDA has received comments and suggestions on the Y2K Clearinghouse from the National Patient Safety Partnership (NPSP). NPSP is an association of organizations with interests in improving and promoting patient safety in medical care. It is organized and supported by the Department of Veterans Affairs through the Veterans Health Administration. Participants include the Department of Veterans Affairs, the Agency for Healthcare Policy and Research, the American Medical Association, the American Hospital Association, the American Nurses Association, the Joint Commission on Accreditation of Healthcare Organizations, the Association of American Medical Colleges, the National Patient Safety Foundation, the Institute for Healthcare Improvement, the Department of Defense, the National Institute of Occupational Safety and Health, and FDA.

One of the recommendations from the NPSP is that, in addition to the database on products with known Year 2000 problems, healthcare facilities and others require access to a database that will provide a single source for information on Year 2000-vulnerable biomedical products that are known to be Year 2000 compliant. The desire for or need for this new information by healthcare facilities was not previously appreciated, but has become more critical as healthcare facilities have become more intensely involved in Year 2000 assessments. The healthcare community, as represented by the NPSP, has requested that the FDA, on behalf of the Federal government, provide the mechanism for this single, comprehensive source of information concerning both Year 2000 compliant and non-compliant biomedical products.

2. How Information Will Be Used

Through a letter sent by the Director, Center for Devices and Radiological Health, FDA, and accompanying instructions (attachment 2), manufacturers of biomedical equipment known to be Year 2000-vulnerable will be asked to provide a list of products that have been evaluated and found not to be impacted by the date issue. The information requested will include the specific manufacturer, product type, model number and version number of each product evaluated by the manufacturer and determined to be compliant. The request will also ask for a single point of contact at the manufacturer to discuss product information, including information on testing protocols.

The manufacturer will be able to provide the information directly to government web site via the Internet or provide electronic or paper copy of the information to the FDA for inclusion in the web site database. The provision of information will signify that the information provided is true to the best of the manufacturer's knowledge. Government agencies, as well as healthcare facilities and the general public, will have access to the web site and will use the information to assess currently owned equipment as well as to evaluate potential acquisitions. The posting of information on compliant products is designed to provide healthcare facilities with a positive statement as to the status of compliant products. It will also provide an opportunity for manufacturers to communicate and better serve customers in a responsible and proactive manner, and avoid the necessity for manufacturers and vendors to field numerous calls and letters from individual organizations.

3. Use of Improved Information Technology

As noted above, manufacturers will be encouraged to provide their information electronically for posting on the government web site, or directly via the Internet to the government web site. Government agencies and the general public will have access to the web site. The capability will be provided for users of the web site database to retrieve a copy of the entire database via an electronic file transfer or paper printout for use in their Year 2000 remediation efforts.

4. Efforts to Avoid Duplication

The FDA letter and the accompanying information request for compliant product information from manufacturers will be sent on behalf of all the agencies represented in the Biomedical Equipment Subgroup and the NPSP, thus eliminating the duplication which would occur if each agency independently collected the information. Furthermore, the collection of this information provides a public benefit through the posting of the information on a web site. The government web site will reduce the burden on both government agencies and the private health care industry by providing a single source of information on the Year 2000 compliance status of biomedical equipment.

5. Small Businesses

In the collection of product information, manufacturers are asked to identify the Year 2000-compliance status for only those products that are Year 2000-vulnerable, i.e., products, which are electrical and might use computer control or processing. This eliminates the burden of listing every, non-electrical product they manufacture. As part of their preparation for the Year 2000, manufacturers should already have conducted product testing and should have this information readily available for all of their products – they do not need to perform additional testing or assessments to respond to this collection of information. Furthermore, the product information requested, along with the compliance status, includes only information needed to adequately identify the product. By posting the information on a web site available to the public, the manufacturer will field a reduced number of calls and letters on product compliance from individual organizations. The burden reduction is true for all manufacturers but applies more significantly to small businesses.

6. Consequences if Information is Not Collected

This information is needed to prevent any potentially adverse health and safety consequences due to the malfunctioning of biomedical equipment as a result of the Year 2000 date problem. All agencies and healthcare facilities have been advised to verify the Year 2000 compliance of critical biomedical products, product by product. Without this additional information from manufacturers, government agencies as well as private health care organizations will not have an affirmative assurance that their currently owned biomedical equipment is Year 2000 compliant nor will they be able to adequately assess choices for new acquisitions of this equipment. If individual government agencies and

private health care organizations individually contacted manufacturers regarding their products, the burden for all involved would increase significantly. A single collection and a posting to the web site will provide the needed information in the most efficient and timely manner and therefore protect the health and safety of the public.

7. Special Circumstances

Not applicable.

8. Consultation

The Emergency Federal Register Notice will provide an opportunity for public comment.

In addition, the FDA, through participation in the NPSP has met with the Health Industry Manufacturers Association, the National Electrical Manufacturers Association, and the Medical Devices Manufacturer's Association and several individual manufacturers to discuss steps that could be taken to improve the quality and quantity of the information in the current database and to enhance its utility to healthcare organizations. While manufacturers have been supportive of the current database on Year 2000 non-compliant products, they have expressed concerns about the added utility of a single, comprehensive database for Year 2000 compliant products, noting that the currently provided information on non-compliant products should meet the information needs of healthcare facilities. They acknowledge, however, the overwhelming desire for such a database from the users of biomedical products.

In order to assist manufacturers to rapidly and efficiently comply with the collection, a telephone hotline will be established to provide a single source of assistance to manufacturers in submitting the requested data.

9. Remuneration

There is no remuneration of respondents.

10. Confidentiality

The letter will inform manufacturers that the information they voluntarily post on the web site or provide either electronically or on paper for posting, will be available to government agencies and to the general public.

11. Sensitive Questions

The survey will not request sensitive information.

12. Burden Estimates

Table 1--Estimated Annual Reporting Burden¹

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| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 3,500 | 1 | 3,500 | 12 | 42,000 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated total annual burden levied on respondents for this collection of information on biomedical equipment is derived from estimates of the number of manufacturers of Year 2000-vulnerable products, the number of compliant products, and the estimated amount of time needed for reporting products, with allowance for variation in the number of products to be reported by a manufacturer.

Based on FDA mailing lists and experience with the database on non-compliant products, the number of manufacturers of Year 2000-vulnerable medical devices is estimated at no more than 2,500. While input from the Analytic Instrument Association, the number of manufacturers of Year 2000-vulnerable scientific laboratory products is estimated to be less than 1,000. Therefore, the total number of manufacturers that will receive the request to submit information will be less than 3,500.

The estimate for medical device products was derived from the number of premarket submissions made to FDA since 1976 and information on the proportion of product types which are expected to be Y2K-vulnerable. FDA does not have access to information that would characterize the total number of products which may be subject to reporting under this request. FDA has data on the number of premarket notification and premarket applications and supplements that have been approved since establishment of the medical device regulatory program. This data provides information on the number of new products that could have been brought to market based on the number of FDA clearances to market. However, there is not a one-to-one correspondence between the number of products cleared by FDA and specific, distinct product models introduced by the manufacturers. It is possible that multiple product models are marketed under a single premarket clearance, with only minor or insignificant differences between the models. Therefore, estimates based on the number of premarket clearances granted are uncertain but provide the only basis for this estimate. It is also possible that products cleared for market more than 10 years ago are no longer in use or that products receiving clearance were never actually marketed.

In addition, definitive data is not available on the proportion of product types or distinct models that are either electrically powered (as a surrogate for potential Year 2000 date problem vulnerability) or that actually use dates in their operation. An analysis of the distinct product codes used by FDA to track different types of products identified 869 of the 4,807 product codes as being for product types likely to be computerized and thus Year 2000 vulnerable. Applying this proportion (about 20 %) to the total number of premarket clearances (about 110,000) results in an estimated 22,000 Year 2000-vulnerable medical device products which have been cleared for market. This estimate has a large

uncertainty as described above.

For scientific laboratory equipment we have no information on the number of Year 2000 vulnerable products. Each manufacturer was estimated to have potentially two products that involved dates; therefore, the estimated number of Year 2000-vulnerable products is less than 2,000. Therefore, the total estimated number of Year-2000 vulnerable biomedical products is 24,000. Of these products, some are non-compliant and would thus not be included in this data collection effort. The number of these non-compliant products is currently not known, but based on the current database, the number is expected to be less than 4,000. (Currently, information on non-compliant products is provided both on the FDA operated web site and web sites operated by manufacturers, therefore no total count of non-compliant products is available.) Thus, the estimated number of compliant, Year 2000-vulnerable products that is subject to this collection is expected to be about 20,000.

The manufacturers of biomedical devices are already required to assess the Year 2000 compliance of their products to satisfy business, liability and regulatory concerns. Therefore, the burden estimate assumes that manufacturers have developed information on the Year 2000 compliance status of their products independent of this request. The burden estimate includes simply the time to provide information for the products, not the time to assess the Year 2000 compliance of the products. Information may be provided on-line via the web site. Or, the manufacturer may provide the government with information as either an electronic (e.g., a spreadsheet or specified file format) or a paper record. Based upon experience gained from the current database, it is estimated that the time required for a manufacturer to provide the data on a single product will be less than 5 minutes per product, regardless of the reporting mechanism. (For electronic file submissions that involve the transfer of data for a large number of products simultaneously, this estimate of time per product is an overestimate.) Further, it is estimated that 60% of responses will be collected electronically (10% on-line and 50% by submitting an electronic record) and that 40% of the responses will be submitted on paper. Therefore, an upper limit on the burden estimate for submitting records on Year 2000-vulnerable biomedical products that are Year 2000 compliant is 20,000 products multiplied by 5 minutes per product, or 1,667 hours.

In addition to the actual submission time, manufacturers will require time for consideration of this request, collection of records and formatting of the data. Manufacturers with large number of products will require more effort. This may be estimated by 500 manufacturers requiring 20 hours of preparation and 3,000 manufacturers with smaller product lines requiring 10 hours of preparation, for a total of 40,000 hours. An estimate of the total time required of all manufacturers is thus 41,667 hours.

The average hours per response (one response per manufacturer) is equal to the estimated total hours (41,667) divided by the number of manufacturerers (3,500), or 11.9 hours per manufacturer. This was rounded up to the next whole hour, or, an estimated 12 hours per response.

At a cost of \$50.00 per hour, the estimated cost to respondents is \$2,100,000. Note that the

actual labor costs incurred by manufacturers for much of this effort will likely be less than \$50.00 per hour.

13. Other Costs to Respondents

No additional costs to the respondents are identified.

14. Government Costs

The estimated cost to the government for this collection and the necessary follow-up is \$2,208,050.

The government costs include the printing and mailing of the letter and enclosure as well as the development and maintenance of a web site for posting the information. The printing cost for the initial letter to manufacturers is estimated at \$1,400. The postage and mailing will cost 75 cents a letter. Multiplied by 3,500 letters, the total mailing cost equals \$2,625. Two letters are currently planned for a total mailing cost of \$8,050. Additional, follow-up letters and other actions may be required to solicit participation by manufacturers who do not respond to the initial request for compliant data. Those efforts are not identified at this time and are not included in these estimates.

The estimate for the creation and maintenance of the web site database through June 2000 is \$2,200,000. This includes the design and development of the database, performing and monitoring initial data entry, telephone hotline support, data analysis, annual system maintenance, and an estimated FTE cost for the project. Adding the printing, mailing, and web site costs together results in an estimated cost of \$2,208,050.

15. Change in Burden

This is a new information collection resulting in a single time burden increase.

16. Plans for Analysis and Publication

No statistical analysis of the information is planned.

17. Display of Expiration Date

The expiration date will be displayed.

18. Exceptions to Certification

There are no exceptions to certification.