



DEC 14 1999

Dear Manufacturer:

As you are well aware, a great deal of attention has been paid to possible computer glitches due to the transition to the Year 2000 (Y2K). Of significant concern to the Food and Drug Administration (FDA) has been the effect of Y2K on the availability of medical products, including drugs, biologics, and medical devices, to the consumer.

In order to provide some assurance to the public that the supply of medical products will not be interrupted at the end of this year, FDA has conducted a number of exercises to obtain information from manufacturers of drugs, biological products, and medical devices about their readiness for the Year 2000. Let me take this opportunity to thank you for providing information to FDA about your readiness for the year 2000. I very much appreciate the time and attention you have given the FDA activities aimed at this issue. As a result of the tremendous response we received to the survey and audit programs, we are able to provide the message to the public that we do not foresee interruptions in the supply of medical products because of potential Y2K computer glitches.

We acknowledge that there may be unforeseen events that occur because of Y2K, some of which may impact on your ability to produce and distribute medical products. FDA's Office of Regulatory Affairs has established an Emergency Operations Center (EOC) to handle any reports of Y2K-related failures experienced by manufacturers of FDA-regulated products. The EOC, in conjunction with other components of FDA, is prepared to address any emergency situations that occur at the turn of the year.

In the event that you experience any emergency situations related to your FDA-regulated products, please contact FDA's EOC as soon as possible at 301-443-1240, or by fax at 301-443-3757.

In addition to emergency situations, you may experience other significant manufacturing disruptions because of Y2K. It would be very helpful to us if these were reported to the EOC as soon as you become aware of them, so that we might help ensure they are properly addressed. The incidents should also be reported through the other FDA reporting mechanisms, such as error and accident reports, as appropriate.

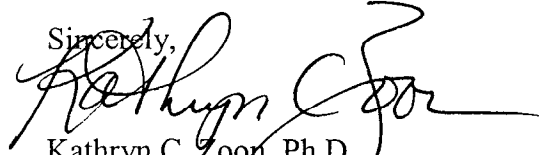
Concerns have also been raised about the possibility of shortages, due either to hoarding of products before the turn of the year or because of manufacturing problems after the turn of the year. It would be very helpful to FDA if you could advise us if you note any shortage issues regarding the supply of your products. If you encounter these situations, please advise CBER's product shortage coordinator, Alice Godziemski, as soon as possible. She can be reached at 301-827-6220, by email at

Godziemski@CBER.FDA.gov, or by fax at 301-827-6748. Early reporting of potential shortage situations will enable FDA to take actions to try to prevent any impact on patients.

To further manage any potential shortages, it would be very helpful to us if you were to provide information about your available inventory as of December 20, 1999. This is not a regulatory requirement, but will enable FDA to more quickly respond to any potential shortage situations. This information will be used only in the event of reported product shortages. These lists should also be directed to Ms. Godziemski.

Thank you for your continued cooperation in helping FDA to ensure the continued availability of medical products in the Year 2000. If you have any questions, please contact Jennifer Thomas, Office of Compliance and Biologics Quality, at 301-827-6190 or by email at thomasj@CBER.FDA.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kathryn C. Zoon', written in a cursive style.

Kathryn C. Zoon, Ph.D.

Director, Center for Biologics

Evaluation and Research