DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dear President/CEO/Blood Establishment Director:

The purpose of this letter is to request your assistance in assuring the Agency and the American public that your firm has addressed the year 2000 (Y2K) problem as it affects the adequate supply of safe and effective biological products to Americans.

The Y2K problem can cause a variety of errors in how dates are expressed or computed that could adversely affect automated process controls and clinical and non-clinical data integrity. Y2K is an issue that, if not addressed by you, could adversely affect the safety and health of the American public. It is also important that suppliers to your firm have Y2K compliant systems because a disruption in the flow of components, packaging materials, and equipment, for example, could halt or slow the production of biological products, even if your firm has Y2K well under control. I therefore urge you to work with your suppliers to ensure there will be a minimum of disruption. Of special concern are manufacturing processes, which if disrupted by Y2K could result in severe shortages of needed biological products. An additional concern is the possibility of increased production demands because of distributor and consumer stockpiling of critical products.

It is the agency's expectation that manufacturers will do all they can to ensure that their systems are Y2K compliant and give the highest priority to addressing this issue. Manufacturers should thoroughly review and test all computer systems and have appropriate contingency plans in place before January 1, 2000. All procedures to achieve this goal should be appropriately tested and validated prior to implementation. Manufacturers should also establish policies and procedures to monitor consumer demand and to ensure that unwarranted stockpiling beyond normal levels that taxes production capacity does not compromise product availability to all customers.

We request that you complete the attached survey concerning the status of actions taken to address the year 2000 problem. Documentation regarding the steps you have taken to prepare for the year 2000, including this survey, should be available for FDA review during inspections. This special Year 2000 data gathering request is being made pursuant to section 4(f) of the Year 2000 Information and Readiness Disclosure Act. We will use the information you provide to inform the American public about the Year 2000 readiness of the pharmaceutical and blood establishment industries. Therefore, your answers to questions 1, 1a, 7, and 8 of the attached survey may be made available to the public via FDA’s Internet site (www.fda.gov). Answers to questions 2 through 6 in the survey will be protected under section 4(f) of the Year 2000 Information and Readiness Disclosure Act. However, aggregate data may be made available to the public.

In order to provide the best service to the industry and public, as well as recognizing the limited time available before the Year 2000, we ask that all manufacturers respond to the attached Y2K Assessment survey within 15 days of the receipt of this letter to:

FDA Y2K Survey
1101 Olivette Executive Pkwy.
Suite 200
St. Louis, MO 63132 - 9709

Fax: 1-888-574-1327

In addition, we ask that you provide us with timely updates on any pertinent Y2K compliance issues that might surface after completion of the attached survey.

Licensed manufacturers that make changes to their manufacturing processes to become Y2K compliant should report these changes to CBER in the appropriate format (supplement or annual report), according to current regulations and guidance. If a manufacturer files a supplement to an approved application for manufacturing changes made for the purpose of making manufacturing processes Y2K compliant, the supplement should be labeled as Y2K-related. If possible, supplements for Y2K-related changes should be submitted separately from supplements for other changes, unless the changes are related such that they cannot be submitted independently.

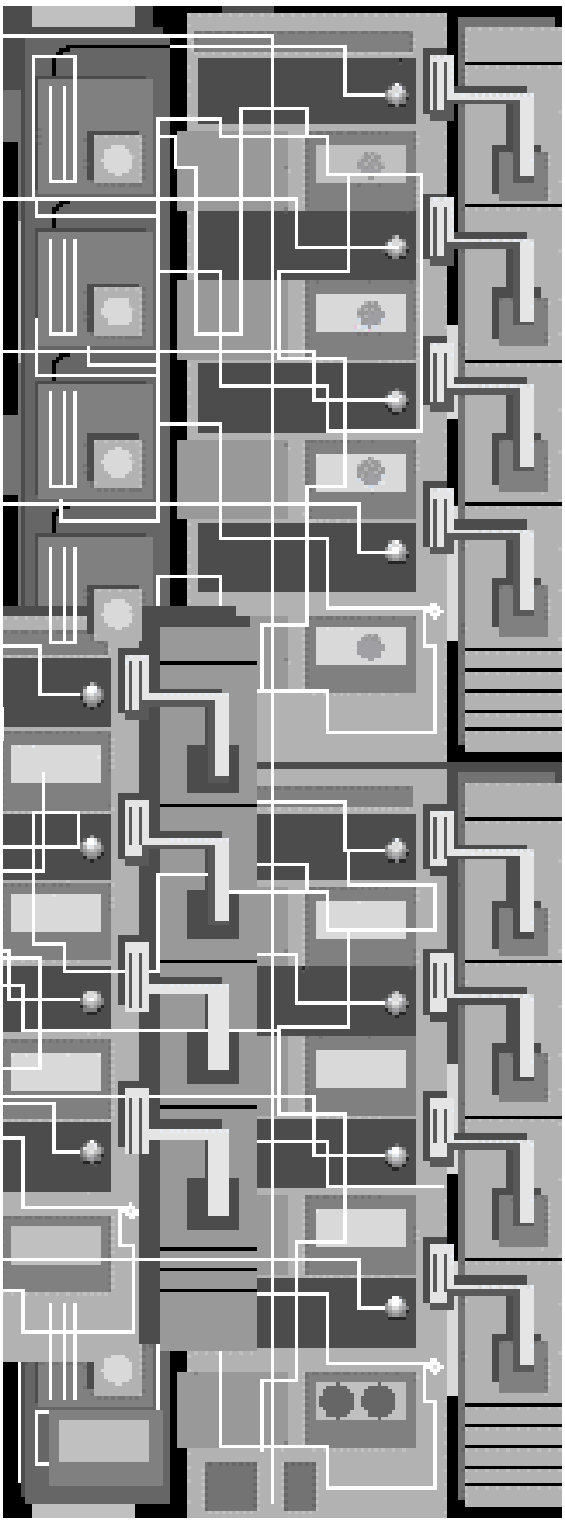
On a personal note, I know that you share our commitment to the uninterrupted provision of our nation's vital drug supply. If you have further questions, you may contact Jennifer Thomas, CBER, OCBQ Associate Director for Policy, at (301) 827-6190. Thank you for your cooperation.

Sincerely,

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
Attachment

ID Label here

OMB #: 0910-0408
Expiration: 11/30/1999



Y2K Assessment Survey

Center for Biologics Evaluation and Research US Food and Drug Administration

June 1999

Y2K Assessment Survey
Center for Biologics Evaluation and Research

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Company Name: _____

Company Address: _____

_____

License Number or Registration/CFN Number(s): _____

_____

Name, Title, Phone Number and Email address of Y2K Coordinator (or contact):

Y2K Coordinator (contact): _____

Title: _____

Phone Number: (☐☐☐) ☐☐☐ - ☐☐☐☐

Email Address: _____

Do you do business (i.e. distribute your products) under another business name?

❑ YES **(PLEASE RECORD NAME AND ADDRESS)**

❑ NO

Other Business Name: _____

Address: _____

_____

1. Does your organization have a plan for addressing the Y2K problem?

❑ YES

❑ NO

A. Have you taken all steps necessary to ensure that the information technology and automated systems (e.g., manufac-turing, quality control, in-house distribution systems) used in the facilities responsible for producing all your FDA-regulated products are Y2K compliant*? **Please update us when any significant change in your status occurs.**

❑ YES **(SKIP TO QUESTION 2)**

❑ NO

What date do you anticipate completing this task?

DATE..... ☐☐ - ☐☐ - ☐☐☐☐

MM DD YY

**Compliant means that the automated systems can accurately process date/time data (including, but not limited to, calculation, comparing, and sequencing) from, into, and between the years 1999 and 2000 and perform leap year calculations. This includes identifying all of the systems and correcting and validating any solutions to the problems related to Y2K or implementing workarounds to deal with the problems. In addition, you should have written documentation (e.g., assessments, test results, reports from independent reviewers) to demonstrate that all possible steps have been taken to make the systems compliant or have written documentation of your workarounds.*

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2. Have you initiated or do you plan to initiate an independent review of your Y2K program (i.e., by a group other than the one who did the initial analysis)?

❑ YES ❑ NO **(SKIP TO QUESTION 3)**

A. When will this independent review be completed?

DATE..... ❑❑ - ❑❑ - ❑❑❑❑
MM DD YY

3. Do you have foreign suppliers of materials (e.g., raw materials, equipment) used in the manufacture of your products?

❑ YES ❑ NO **(SKIP TO QUESTION 4)**

A. Have you asked these foreign suppliers about their Y2K readiness?

❑ YES **(SKIP TO QUESTION 4)**
❑ NO

When will this task be completed?

DATE..... ❑❑ - ❑❑ - ❑❑❑❑
MM DD YY

4. Do you have contingency plans (i.e., a plan to deal with potential problems such as problems in obtaining raw materials or in manufacturing, packaging, labeling, or distributing the finished product)?

❑ YES **(SKIP TO 4A AND ANSWER 4A, 4B, AND 4C)**
❑ NO

When do you expect to have one in place?

DATE..... ❑❑ - ❑❑ - ❑❑❑❑
MM DD YY

(SKIP TO QUESTION 4B, 4C)

A. Where appropriate, have the components of the contingency plans been tested?

❑ YES
❑ NO

When do you expect to complete testing?

DATE..... ❑❑ - ❑❑ - ❑❑❑❑
MM DD YY

B. Do the contingency plans address potential problems with your key business partners (suppliers, vendors, and distributors)?

❑ YES
❑ NO

C. Do your contingency plans address potential problems with foreign suppliers (e.g., establishment of alternate suppliers of materials)?

❑ YES
❑ NO

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5. Do you have plans to increase production of your products if you face an anticipated increase in consumer demand due to Y2K concerns?

❑ YES
❑ NO

   A. In response to an expected increase in demand due to Y2K concerns on the part of consumers or actual production or supply problems, is an increase in production feasible at this time (i.e., as of the second quarter of 1999)?

❑ YES
❑ NO

6. Do you anticipate submitting supplements to address any Y2K manufacturing changes? *This question is being asked to help us develop plans for dealing with a potential increase in the number of supplements that may be submitted for review.*

❑ YES
❑ NO

7. Do you have an Internet site that provides information on the Y2K readiness of your company?

❑ YES ❑ NO **(SKIP TO QUESTION 8)**

A. URL? _____

8. Do you have a telephone number or other means to handle inquiries from your customers on your Y2K status?

❑ YES ❑ NO

A. Telephone number? ( ) -

_____ _____

President/CEO/Blood Establishment Director ***Date***

Please note: If your survey response includes information about registered divisions or subsidiaries, please identify these divisions and subsidiaries on a separate sheet and submit this with the survey responses.

Thank you for your time in completing this survey.
If you have further questions, you may contact
Jennifer Thomas, CBER/OCBQ Associate Director for Policy, at (301) 827-6190.

Please return this completed survey *and any attachments* to us
in the enclosed pre-addressed, postage-paid envelope or if you prefer,
fax to: 1-888-574-1327.

FDA Y2K Survey
1101 Olivette Executive Pkwy., Suite 200
St. Louis, MO 63132 – 9709