Center for Drug Evaluation and Research's

Interim Report

Assessment of the Pharmaceutical Industry's Readiness for Year 2000

October 18, 1999
Food and Drug Administration

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Assessment of the Pharmaceutical Industry's Year 2000 Readiness

I. What is the problem with computers and Year 2000?

Consumers have heard about the Year 2000 computer problem. Most businesses, including the pharmaceutical industry, are faced with solving potential problems with their operations, known as the “Year 2000 Problem,” “Millennium Bug,” or “Y2K Problem.” Although the Year 2000 computer problem may have many names, they all mean the same thing and can cause a variety of errors in date expression and computation.

The Year 2000 or Y2K problem arises because a number of computerized functions require recognition of a specific year, day, and time, but many computers and computerized equipment recognize only the last two digits of a year’s date. This problem began many years ago when, to conserve memory space, programmers used two numbers to record the year. Unfortunately, computers and microchips that still rely on a two-number year may, on January 1, 2000, recognize “00” as 1900 rather than 2000. As a result, equipment with embedded computer chips and computers may not function properly. Others may continue to operate, but erroneously, while others simply may stop and need to be restarted.

Many pharmaceutical drug products are manufactured, packaged, labeled, or distributed using automated computer systems and are potentially vulnerable to Y2K computer problems. The millennium bug may cause changes in how dates are expressed or computed, which could affect automated drug process controls, clinical and non-clinical data integrity, post market reporting, distribution of drug components and finished products. However, the pharmaceutical industry has taken many steps to prepare for Y2K and to reassure the American public that medicines will continue to be available through the millennium rollover.

II. What is FDA's role?

The Center for Drug Evaluation and Research (CDER) promotes and protects public health by helping to assure that safe and effective drugs are available to Americans. CDER is working hard to ensure that drugs are manufactured in accordance current good manufacturing practices and that the computer systems work properly before, during, and after the Year 2000.

Consumers should be aware of the necessary actions the agency has taken to ensure the pharmaceutical industry is ready for Year 2000. Assurance from the pharmaceutical

industry is critical because a disruption in the flow of components, packaging materials, and equipment, for example, could halt or slow pharmaceutical production, which could result in shortages of needed pharmaceuticals. An additional concern is the possibility of increased production demands because of distributor and consumer stockpiling of critical supplies and pharmaceuticals. In order to provide this assurance, FDA decided to make an assessment of the industry.

There is generally a 60-90 day supply of product in the distribution chain.[1] Unless there has been pre-existing hoarding, transient manufacturing issues including those related to Y2K will not affect product availability because most Y2K problems will be fixed within 3-5 days.[2]

As we approach the new millennium, CDER is committed to keeping the public informed and assured that pharmaceutical companies will be able to continue to supply safe and effective drugs to consumers. This report will be updated as new information on the industry's readiness becomes available.

III. How was an assessment of the pharmaceutical industry made?

An assessment of the industry was made in two phases. The first phase consisted of surveying the pharmaceutical industry to develop an overall picture of its readiness. The second phase consisted of an audit program. The audit program was intended to confirm the results of the survey program that adequate steps have been taken by the industry to be ready for Year 2000. Both programs were voluntary on the part of the industry. However, many steps were taken to obtain a high response rate that is representative of the industry.

We placed particular emphasis on the prescription drug manufacturers. Of the prescription drug manufacturers, primary focus was placed on a subset of manufacturers identified as 'priority companies.' Priority companies are those prescription drug manufacturers of sole source, orphan, or top 200 prescribed drug products.

The Agency designated much of the information related to a particular company gathered under the survey and audit programs as confidential under section 4(f) of the Year 2000 Information and Readiness Disclosure Act. However, we are making available aggregate data.

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[1]President's Council On Year 2000 Conversion, Pharmaceutical Industry Roundtable June 14, 1999, "Refill Guidance Document," June 14, 1999.

[2]Gartner Group (J. Cassell, J. Bace, J. Baylock, B. Conway, C. Dreyfuss, J. Duggan, B. Hayward, M. Hotle, R. Hunter, E. Juri, E. Keller, A. Kyte, S. Levin, W. Malik, L. Marcoccio, B. McNee, A. Percy, A. Cushman), Strategic Analysis Report,*Year 2000 Risk Assessment and Planning for Individuals* , October 28, 1998.

IV. What were the methods used to perform the survey and audit programs?

A. Survey

A survey was developed to determine the overall readiness of the industry (Attachment A). The survey was designed to be brief to ensure a high completion rate and yet be comprehensive enough to ensure we collected meaningful information. Question 1 of the survey was developed as the primary question of readiness (i.e., Have you taken all necessary steps to assure that the information technology and automated systems (e.g., manufacturing, quality control, distribution systems) used in the facilities responsible for the safe and effective production and distribution of all of your products that will be distributed in the United States are Y2K compliant?). Other questions were developed to reinforce and confirm the answer to question 1.

The survey was distributed on April 21, 1999, to prescription and over-the-counter drug manufacturers, bulk drug manufacturers (i.e., manufacturers of active raw material), distributors, repackagers, and medical gas manufacturers. The survey requested a reply within 15 days upon receipt. The initial mailing list of 4228 companies was developed from our Drug Registration and Listing System (DRLS). Following is a breakdown of the numbers of companies sent the survey.

Table 1 - Companies Surveyed

Category	Number Surveyed
1. RX Manufacturers (RX)	1070
2. OTC Manufacturers (OT)	474
3. Bulk Manufacturers (BU)	1233
4. Distributors/Repackers (DI)	392
5. Gas Manufacturers (GA)	1059
TOTAL	**4228**

Attachment B identifies the priority companies.

Although the cover letter to the survey (see Attachment A) indicated that we were asking for the company's consent to release their answer to question 1, a majority of the companies have requested that this information not be released and did not consent to the release of this information. Therefore, answers to questions 1 through 6 will be reported only in the aggregate. This information will be kept confidential under section 4(f) of the Year 2000 Information and Readiness Disclosure Act.

In order to maximize the response rate, we used several follow-up programs.

- On May 24, 1999, a reminder notice was sent to approximately 650 nonresponding prescription drug manufacturers.

- On June 22, 1999, a memo was sent to four prescription drug manufacturer trade organizations (i.e., Generic Pharmaceutical Industry Association (GPIA), National Association of Pharmaceutical Manufacturers (NAPM), National Pharmaceutical Alliance (NPA), and Pharmaceutical and Research Manufacturers of America (PhRMA)) soliciting their assistance in increasing the response rate (see Attachment C).

- On July 1, 1999, a reminder notice was sent to 936 domestic nonresponders (via postcard) and 883 foreign nonresponders (via letter).

- On September 8, 1999, a reminder notice (with another copy of the survey) was sent to 594 domestic (including Canada and Puerto Rico) nonresponders.

- In addition to the various letters and memos, a telephone campaign was launched on June 28, 1999. All domestic and, where feasible, foreign companies were included in the telephone followup program. However, particular emphasis was placed on the priority companies and prescription drug manufacturers.

B. Audit Program

The second phase of the assessment program involved the audit program. The audit program was intended to provide a validation of the survey through extensive telephone interviews and site visits for a sample of the companies.

The interviews and site visits were conducted under contract by information technology experts. FDA's contractors interviewed the individuals in the company who were familiar with the companies' Y2K efforts. The questions were intended to verify the survey responses and provide further information on the industry's readiness for Year 2000 (see Attachment D).

Approximately 180 companies were selected for the audit program. The sampling included all priority companies as well as a random sampling of nonpriority companies that had inconsistent, incomplete, or no response to the survey, or indicated that they would not be ready for Year 2000 until after September 30, 1999.

Most companies were selected for a telephone interview; however, some larger companies opted for a site visit. In addition, the companies who were identified through the telephone interview as potentially having a Y2K-related

manufacturing problem, were also scheduled for site visits. The site visits in the latter this case were intended to collect more information on the company's contingency plans and to further assess their readiness. All randomly selected nonpriority companies were also selected to participate through the site visits rather than telephone interviews.

If a priority company refused to participate after initial contacts from the contractor, several attempts were then made by FDA employees to request participation. If the company still refused, we then evaluated their products to determine if they made any products that should be available to the public without any disruptions in supply. Many sole source, orphan, or top 200 products are products for which adequate alternatives are available. If a company made a product for which other sources were not available or for which there was no adequate alternative therapy, then the company was encouraged to participate via a letter from the Center Director. If the company still refused to participate, an FDA investigator inspected the company to collect the necessary information on Y2K readiness.

If a randomly selected nonpriority company refused participation in the audit program, another nonpriority company was randomly selected.

At the conclusion the telephone interview or site visit by the contractor, each company was rated according to the following categories.

- Green: Item on track, issues known & appropriate actions planned (with Caution: Minor Issues)
- Watch: Potential major issues (no known problems, but there may be trouble lurking)
- Yellow: Critical issue impacting success (trouble identified)
- Red: Item is behind, out of control, or well over budget (serious difficulty that will likely prohibit success)

The final interview/site visit report was sent to the company to make sure that there was no misrepresentation of information.

V. What are the results of the survey and audit program?

A. Survey

1. Overall Response

Overall the industry was very cooperative in responding to the survey. Most either completed the survey, provided a form letter stating their

readiness, indicated they were subsidiaries of another company, or no longer in the business. In all cases, companies who indicated they were subsidiaries of another company, information from the parent company was received. The following table summarizes the overall responses.

Table 2 - Overall Response Rate to Survey
(As of October 15, 1999)

Responses	RX	OT	BU	DI	GA	Total
1. Response as Subsidiary	212	20	89	46	47	**414**
	19.8%	4.2%	7.2%	11.7%	4.4%	**9.8%**
2. Surveys Completed (via mail or phone)	630	311	438	232	796	**2407**
	58.9%	65.6%	35.5%	59.2%	75.2%	**56.9%**
3. Form Letter (FL) Received	20	9	34	10	31	**104**
	1.9%	1.9%	2.8%	2.6%	2.9%	**2.5%**
4. Returned In Mail	2	30	182	27	22	**263**
	0.2%	6.3%	14.8%	6.9%	2.1%	**6.2%**
5. Out of Business	192	8	10	6	7	**223**
	17.9%	1.7%	0.8%	1.5%	0.7%	**5.3%**
6. No Response	14	96	480	71	156	**817**
	1.3%	20.3%	38.9%	18.1%	14.7%	**19.3%**
TOTAL	**1070**	**474**	**1233**	**392**	**1059**	**4228**
COMPLETION RATE	1054	348	571	294	881	**3148**
(Subsidiary + Surveys + FLs + Out of Business)	98.5%	73.4%	46.3%	75.0%	83.2%	**74.5%**

Of those companies who submitted form letters, attempts were made to encourage them to complete the survey. In some instances, the form letters were very detailed and it was possible to extract information on the Y2K readiness of the company and answer the survey questions.

As described above, the initial mailing list was developed from the Drug Registration and Listing System. This system is dependent on the industry to provide updated information (e.g., new addresses, status of business), therefore a small percentage of survey's were returned in the mail. Every attempt was made to contact the company or to determine its status. We took further steps to assess the products made by the prescription drug manufacturers whose surveys were returned in the mail. Most of these were identified through other internal databases as companies who no longer make finished drug product for the United States. For the purposes of reporting the survey results, these companies were considered to be out of business.

2. Prescription Drug Manufacturers Response

A very high completion rate was observed for the prescription drug manufacturers, i.e., 98% of the companies answered the survey questions, provided a form letter, indicated they were subsidiaries of another responding firm, or were identified as being out of business. Of the firms completing the survey, 73% said they have already taken all necessary steps to prepare for Y2K. The vast majority of others indicated they will be ready by the end of October, 1999.

The telephone follow-up campaign also included calling those companies that indicated they would be ready at a future date (i.e., in June, July, August, and September) to update their status.

Of those, the prescription drug manufacturers that completed the survey 94% indicate that they will be ready for Year 2000 by the end of October 1999.

3. Priority Company Response

The completion rate for the priority companies was similar to that of the prescription drug manufacturers (98%). Any priority company that did not complete a survey was evaluated during the audit program. The following table shows the overall responses from the priority companies as well as their answers to Question 1.

Table 3 - Priority Company Response Rate
As of October 15, 1999

1. Response as Subsidiary	112
	40.9%
2. Surveys Completed (via mail or phone)	150
	54.7%
Yes to Q1	93
No to Q1	57
Steps by 6/99	9
Steps by 7/99	6
Steps by 8/99	4
Steps by 9/99	21
Steps by 10/99	9
Steps by 11/99	2
Steps by 12/99	4
No date indicated	2
3. Form Letter Received	4
	1.5%
4. Returned In Mail	0
	0.0%
5. Out of Business	4
	1.5%
6. No Response	4
	1.5%
TOTAL	**274**
COMPLETION RATE	270
(Subsidiary + Surveys + FLs + Out of Business)	98.5%

The responses to question #1 for the priority companies were similar to that of the overall prescription drug industry, i.e., 95% indicated they will be ready for Year 2000 by then end of October 1999. All of the priority companies were included in the audit program to confirm the survey results and to confirm that those indicating a late readiness date (i.e., after September 30, 1999) would meet their goals.

4. Foreign Country Response

Of the 4228 companies that were surveyed, approximately 1775 were foreign companies. We believe we have taken all reasonable steps to obtain survey results from foreign companies and have succeeded in obtaining a 63% response rate. Foreign companies completing the survey indicate that their overall readiness for Year 2000 is similar to the readiness of domestic companies. In addition, of those domestic firms

using foreign suppliers, at least 82% have already asked their foreign suppliers of their Y2K readiness and at least 75% have already addressed potential problems with foreign suppliers in their contingency plans.

5. Comparison of Results

The following table compares the results of the various categories.

Table 4 - Comparison of Survey Results
As of October 15, 1999

	Priority Companies	All Rx Manufacturers	All Companies	Foreign Companies
% Responded	**98.5%**	**98.5%**	**74.5%**	**62.9%**
%Completing survey (excluding subsidiaries)	**92.3%**	**73.4%**	**63.1%**	**43.6%**
% Answered that they are ready for Y2K	**62.3%**	**71.4%**	**80.6%**	**74.0%**
% Will be ready by 10/30/99	**94.7%**	**93.6%**	**94.4%**	**95.1%**

More detailed results of the survey program are shown in Attachment E.

B. Audit

After conducting several pilot telephone interviews, the audit phase was fully launched on August 2, 1999. The pharmaceutical industry was also cooperative in participating in this program. The audit program will continue until all the necessary information is obtained.

Telephone/site visits were planned with 161 priority companies and 22 nonpriority companies. As of October 15, 1999, 88% of the audits have been completed. Results to date are positive and have confirmed the survey results and our expectation that the industry has taken necessary steps to prepare for Year 2000. Of those that have been completed and rated, 92% have rated green, 6% rated green with caution, 0.7 % watch, and 0.7% yellow. One firm

initially rated red, however, after a site visit, this firm was upgraded to green with caution. This firm makes only one product and has an additional 6 month supply of product on hand. Also, after initial telephone interviews two firms rated 'yellow' and two firms rated 'watch;' however, only two of those companies make a product that we believe is important and no disruption in supply should occur. After site visits to these two firms, both firms were upgraded (one was upgraded to green and the other was upgraded to green with caution).

During the initial scheduling, 3% of the firms refused participation (2 priority companies and 4 nonpriority companies). Of the priority companies who did not wish to participate, we reviewed their product line and, if necessary, the company was inspected by FDA to obtain the information.

Complete results of the audit program are shown in Attachment F.

VI. What are the plans if a problem is identified?

Year 2000-associated problems are only a subset of the wide variety of problems that CDER routinely deals with, including manufacturing problems with the potential for affecting the supply of drugs. In most cases, the Center does not become aware of drug shortages until after they occur. However, Year 2000-associated problems allow CDER to take actions earlier to help prevent any drug shortages. Potential and actual shortages of drugs often occur due to a variety of manufacturing problems. CDER has a standard policy for dealing with drug shortages (MAPP 4730.1).[3] FDA will distinguish between normal disruptions in drug supply and those due to Y2K-related problems. Some Y2K-related drug shortages may be due to problems unrelated to the manufacturing process.

FDA will monitor the consumer demand through various mechanisms. The potential for drug shortages due to manufacturing issues will be assessed through the Y2K survey and audit program, as well as established procedures for dealing with drug shortages and manufacturing problems.

We will pay particular attention to potential shortages of those important products that are used to treat or prevent a serious aspect of a serious disease or medical condition and for which there is no adequate alternative for that use. Patient or practitioner "inconvenience" alone is an insufficient basis to decide that a need exists for a product. Cost generally is not considered. (Note: This is the same definition used in the standard procedures when the agency deals with drug shortages.)

Notification that there *may* be a potential drug shortage will be given to health care practitioners beginning on or about December 1, 1999, if

[3] Center for Drug Evaluation and Research, Manual of Policy and Procedures (MAPP), 4730.1, "Drug Shortage Management," November 13, 1995.

- the results of an audit and/or an FDA inspection have shown that company is unlikely to be ready for Year 2000 **AND**

- the company produces a important product **AND**

- there is less than a 60 day supply in the distribution chain **AND**

- there is no reasonable expectation that the company will be able to fix the problem within 7 days of the incident **AND**

- it does not appear that the current supply and any additional production will not last until the problem can be corrected or contingency plans can be implemented.

We realize that premature notification to consumers and health care providers regarding a potential problem may lead to increased consumer concern and an increase in hoarding not only of the particular drug in question, but all drugs.

The notification will clearly state that FDA will continue take all necessary steps to help ensure a continued supply of drug. Attachment G outlines the steps FDA will take to accomplish this goal.

VII. How do you plan on communicating information to the public?

CDER's Office of Training and Communication (OTCOM) has developed a comprehensive communication/education outreach strategy aimed at consumers and health care professionals.

CDER's communication/education outreach strategy includes the following:

- Internet communications via FDA/CDER's Web Page (www.fda/gov/cder/y2k)
- Drug Information '1-888-INFOFDA' hotline
- Collaborative interactions with FDA's ORA regional offices
- Partnerships with key health care and trade organizations and associations
- National media educational campaign

A. Target Audiences

For this public education effort, FDA has targeted the general public and health care professionals. In addition, FDA/CDER will work with the Office of Special Health Initiatives (OSHI) to disseminate information to groups and associations with special health concerns (e.g., diabetes association). Language-specific materials will be developed to reach selected audiences.

B. Strategy/Communication Objective

To help alleviate the public's concern about the availability of drug products during the millennium crossover period, the Food and Drug Administration will develop and implement a series of outreach and educational initiatives. FDA plans to reach consumers and health care professionals with educational materials delivered through a variety of channels. Once completed, the general public, consumers and health care professionals will have a clear understanding of the issues concerning drug availability, supply and demand at the onset of the year 2000. These initiatives will:

- discuss the steps drug manufacturers are taking to ensure that sufficient drug products will be available to meet consumer demand for Y2K;
- reassure the public that there is no need to hoard or stockpile drugs for future use;
- provide the public and health care practitioners with information about the availability of drug products;
- promote key messages through communication channels that will reach the general public, consumers and health care professionals;

C. Outreach Methods

FDA will use the following methods to communicate its messages:

Initiative	Target Audience	Timeline
Develop radio and print public service announcements	Consumers Health care providers	October-December 1999
Develop brochures for display at pharmacies and conferences	Consumers Health care providers	October-December 1999
Create a FAQs sheet on CDER Internet site	Consumers Health care providers	August 1, 1999
Publish the results of FDA's drug manufacturer survey on CDER's Internet site	Consumers Health care providers Industry	September-October, 1999
Publish an article in FDA Consumer	Consumers Health care providers	October - November 1999
Publish an CDER Y2K update survey data in Trade press	Industry	September-October 1999
OTCOM write an general Y2K article to be published in NAPS (newswire service disseminated in more than 10,000 newspapers across the	Consumers	August 1, 1999

country)		
Develop Y2K flyer and distribute information at conferences and meetings (e.g. American Public Health Assoc.; AARP conference, Family practice conferences)	Consumers Health care providers	September-October, 1999
Develop partnerships with drug manufacturer associations and National consumer groups to produce and distribute materials through their member communications channels	Consumers Health care providers	October 1999
Create opportunities for FDA personnel to speak/interview with the media	Consumers Health care providers Industry	October-December 1999
Develop talking points for FDA officials for media and trade press interviews	Consumers Health care providers	September-December 1999
Create 1-888 phone tree to respond to callers on the y2k issue	Consumers Health care providers	September, 1999
Distribute information through FDA's district and regional offices	Consumers Health care providers in regional areas throughout country	August-December, 1999

VIII. What are the FDA's recommendations?

The Food and Drug Administration is committed to helping reassure the American public that Year 2000 computer concerns will not affect the supply or availability of drug products.

The Center for Drug Evaluation and Research frequently monitors pharmaceutical companies to determine if important drug products are in sufficient supply. In addition, the Center's survey and audit program have confirmed that, overall, the pharmaceutical industry has taken necessary steps to prepare for the millennium crossover and will generally be able to continue to provide safe and effective drug products now and in the future.

In addition, the pharmaceutical industry has emergency response plans in place and extensive past experience using these plans to handle disruptions caused by severe weather, transportation, or other unforeseen occurrences.

To help consumers prepare for any medical situation at any time, the Center supports the following recommendations to consumers:

- Make a list of prescription and important nonprescription medications being you take.
- Get a normal refill of your medication when you have a 5 to 7 day supply of medication remaining. This is good practice for January 1, 2000 and for any other time. The drug supply system is resilient and can generally correct any issue that might arise within 5 to 7 days.
- Create a personal health record for the entire family.
- Keep records of insurance claims.
- Carry current insurance cards at all times.

IX. What are your follow-up plans?

After January 2000 FDA will compile and evaluate the drug shortage reports received to determine if Y2K had any impact on the drug supply and if additional communication with the public is needed.

Attachment A - April 21, 1999, Survey

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear President/CEO:

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 drugs to Americans.

The Y2K problem can cause a variety of errors in how dates are expressed or computed that could adversely affect automated drug process controls and clinical and non-clinical data integrity. Y2K is an issue that, if not addressed, 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 pharmaceutical production, 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 pharmaceuticals. An additional concern is the possibility of increased production demands because of distributor and consumer stockpiling of critical supplies and pharmaceuticals.

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 industry. Therefore, your answers to questions 1, 7, and 8 of the attached survey may be made available to the public via FDA's Internet site (www.fda.gov/cder/y2k). 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:**

Food and Drug Administration
Center for Drug Evaluation and Research
Attention: Y2K Taskforce; HFD-006
5600 Fishers Lane
Rockville, Maryland 20857

Fax: 301-594-5493

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.

On a personal note, I know that you share our commitment to the uninterrupted provision of our nations' vital drug supply. If you have further questions, you may contact Khyati Roberts, Science Policy Analyst, at (301) 594-6779. Thank you for your cooperation.

Sincerely,

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

Attachment - Y2K Assessment Survey

Y2K Assessment Survey
Center for Drug Evaluation and Research

Name[4] and Address of Company: _____

_____

_____

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

1. Have you taken all necessary steps to assure that the information technology and automated systems (e.g., manufacturing, quality control, distribution systems) used in the facilities responsible for the safe and effective production and distribution of all of your products that will be distributed in the United States are Y2K compliant?[5] (Please update us when any significant change in your status occurs.)
   _____Yes
   _____No (What date do you anticipate completing this task? _____)

2. Do you plan on having an independent organization (i.e., a group other than the one who did the initial analysis) conduct a review of your Y2K program?
   ____Yes (When will this independent review be completed? _____)
   ____No

3. Do you have foreign suppliers of materials (e.g., raw materials, equipment) used in the manufacture and/or distribution of your products? _____Yes _____No

   a. Have you asked these foreign suppliers of their Y2K readiness?
      _____Yes
      _____No (When will this task be completed? _____)

[4] If you do business (i.e., distribute your products) under another business name, please also provide that business name(s).

[5] 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 twentieth and twenty-first centuries, and the years 1999 and 2000 and 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.

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
_____No (When do you expect to have one in place? _____)

   a. Where appropriate, have the components of the contingency plans been tested?
   _____Yes
   _____No (When do you expect to complete testing? _____)

   b. Do the contingency plans address potential problems with your key business partners (suppliers, vendors, distributors & others)? __Yes __No

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

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

   a. If you face an 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[6] to address any Y2K manufacturing changes?
_____Yes _____No _____N/A

7. Do you have an Internet site that provides information on the Y2K readiness of your company?
_____Yes (URL:_____)
_____No

8. Do you have a telephone number or other means to handle inquiries from your customers on your Y2K status?
_____Yes (Telephone number:_____)
_____No

[6] This question is being asked to help us develop rapid response plans for dealing with a potential increase in the number of supplements that may be submitted for review.

Attachment B - List of Priority Companies

(NOTE: This list includes all priority companies, including those that were identified as subsidiaries of other companies).

3M HEALTH CARE LTD
3M PHARMACEUTICALS INC
3M PHARMACEUTICALS PARTY LTD
ABBOTT HEALTH PRODUCTS INC
ABBOTT LABORATORIES
ABLE LABORATORIES INC
AKORN INC
ALCON LABORATORIES INC
ALCON PUERTO RICO INC
ALLERGAN AMERICA
ALLERGAN INC
ALLERGAN LENOIR
ALLERGAN WACO
ALTANA INC
ALZA CORP
AMERICAN HOME PRODUCTS
APOTHECON INC DIV BRISTOL MYERS SQUIBB
ASTA MEDICA AG
ASTRA AB
ASTRA PHARMACEUTICAL PRODUCTION AB
ASTRA PHARMACEUTICALS LP
AYERST LABORATORIES INC
B BRAUN MEDICAL INC
BAKER NORTON PHARMACEUTICALS INC
BARR LABORATORIES INC
BAUSCH AND LOMB INC
BAUSCH AND LOMB PHARMACEUTICALS INC
BAXTER HEALTHCARE CORP
BAXTER HEALTHCARE CORP CARDIOVASCULAR GROUP
BAXTER HEALTHCARE CORP RENAL DIV
BAXTER PHARMACEUTICAL PRODUCTS INC
BAYER AG
BAYER CORP
BAYER CORP CONSUMER CARE DIV
BERLEX LABORATORIES INC
BIO TECHNOLOGY GENERAL LTD
BIOVAIL CORP INTERNATIONAL
BIOVAIL LABORATORIES INC
BLOCK DRUG CO INC
BOEHRINGER INGELHEIM PHARMA KG
BOEHRINGER INGELHEIM PHARMACEUTICALS INC
BRAINTREE LABORATORIES INC
BRISTOL CARIBBEAN INC
BRISTOL ITALIANA SUD SPA
BRISTOL MYERS BARCELONETA INC
BRISTOL MYERS SQUIBB CO
BRISTOL MYERS SQUIBB COMPANY
BRISTOL MYERS SQUIBB LABORATORIES CO
BRISTOL MYERS SQUIBB PHARMACEUTICAL LTD
BRISTOL MYERS SQUIBB SPA
CAROLINA MEDICAL PRODUCTS CO
CARTER WALLACE LTD
CATALYTICA PHARMACEUTICALS INC
CENTEON LLC
CIBA VISION CANADA INC. STERILE MANUFACTURING
CIS BIOINDUSTRIES INTERNATIONAL
CIS US INC
CONTROLLED THERAPEUTICS LTD
COPLEY PHARMACEUTICAL INC
CYTOGEN CORP
DEY LP
DISTA PRODUCTS CO DIV ELI LILLY AND CO
DPT LABORATORIES, LTD.
DUPONT PHARMA
DUPONT PHARMACEUTICALS CO
DUPONT PHARMACEUTICALS COMPANY P R
DURAMED PHARMACEUTICALS INC
ELAN HOLDINGS INC
ELAN PHARMA LTD
ELAN TRANSDERMAL TECHNOLOGIES INC
ELI LILLY AND CO
ELKINS SINN DIV AH ROBINS CO INC
ENDO PHARMACEUTICALS INC DBA ENDO GENERIC PRODUCTS
ENZON INC
FAULDING PHARMACEUTICAL CO
FAULDING PHARMACEUTICALS SUB FH FAULDING AND CO LTD
FAULDING PUERTO RICO INC SUB FH FAULDING AND CO LTD
FENWAL DIV BAXTER HEALTH CARE
FERRING AB
FERRING GMBH
FERRING PHARMACEUTICALS
FH FAULDING AND CO LTD
FISONS LTD
FLEMING AND CO

FOREST LABORATORIES IRELAND LTD
FOREST PHARMACEUTICALS INC
FUJISAWA HEALTHCARE INC
G AND W LABORATORIES INC
G POHL BOSKAMP GMBH AND CO
GD SEARLE AND CO
GENENTECH INC
GENEVA PHARMACEUTICALS INC
GENSIA SICOR PHARMACEUTICALS INC
GENZYME CORP
GENZYME TISSUE REPAIR
GLAXO OPERATIONS UK LTD
GLAXO SPA
GLAXO WELLCOME INC
GLAXO WELLCOME MANUFACTURING PTE LTD
GLAXO WELLCOME, INC.
GLENWOOD LLC
GLOBAL PHARM INC
GLOBAL PHARMACEUTICAL CORP
GOEDECKE AG PARKE DAVIS
HOECHST MARION ROUSSEL DEUTSCHLAND GMBH
HOECHST MARION ROUSSEL CANADA INC
HOECHST MARION ROUSSEL DEUTSCHLAND GMBH
HOECHST MARION ROUSSEL INC
HOECHST MARION ROUSSEL SA
HOECHST ROUSSEL PHARMACEUTICALS DIV
HOFFMANN LA ROCHE INC
HYLAND DIV BAXTER HEALTHCARE CORP
ICN CANADA LTD
ICN PHARMACEUTICALS INC
IMMUNEX CORP
INTERNATIONAL LABORATORIES DIV SOLVAY PHARMACEUTICALS
INTERNATIONAL MEDICATION SYSTEMS LTD
INWOOD LABORATORIES INC SUB FOREST LABORATORIES INC
JACOBUS PHARMACEUTICAL CO
JANSSEN CILAG SPA
JANSSEN PHARMACEUTICA NV
JOHNSON AND JOHNSON PHARMACEUTICAL PARTNERS
KING PHARMACEUTICALS INC
KNOLL AG
KNOLL BV NETHERLANDS DBA BASF PHARMACEUTICALS
KNOLL LABORATORIES DIV KNOLL PHARMACEUTICAL CO
KNOLL PHARMACEUTICAL CO SUB BASF CORP
KOS PHARMACEUTICALS INC
KV PHARMACEUTICAL CO
LABORATOIRES SERONO SA
LANNETT CO INC
LEDERLE ARZNEIMITTEL CYANAMID GMBH
LEDERLE LABORATORIES
LEDERLE PARENTERALS INC
LEDERLE PIPERACILLIN INC DIV AMERICAN CYANAMID CO
LILLY DEL CARIBE INC
LILLY FRANCE
LIPOSOME CO INC
MALLINCKRODT CHEMICAL INC
MALLINCKRODT INC
MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC
MCNEIL CONSUMER PRODUCTS CO DIV MCNEIL PPC INC
MCNEIL PHARMACEUTICAL
MCNEIL PHARMACEUTICAL
MEDEVA PHARMA LTD
MEDEVA PHARMACEUTICALS INC
MEDEVA PHARMACEUTICALS MA INC
MEDEVA PHARMACEUTICALS PA INC
MEDI PHYSICS INC DBA NYCOMED AMERSHAM IMAGING
MEDTRONIC INC
MERCK AND CO INC
MERCK FROSST CANADA AND CO
MERCK SHARP AND DOHME (AUSTRALIA) PTY LTD
MERCK SHARP AND DOHME BV
MERCK SHARP AND DOHME ITALIA SPA
MERCK SHARP AND DOHME LTD
MISSION PHARMACAL CO
MONARCH PHARMACEUTICALS INC
MURO PHARMACEUTICAL INC
MYLAN INC
MYLAN PHARMACEUTICALS INC
MYLAN TECHNOLOGIES
NEXSTAR PHARMACEUTICALS INC
NOVARTIS CONSUMER HEALTH
NOVARTIS CONSUMER HEALTH INC
NOVARTIS PHARMA AG
NOVARTIS PHARMA AG
NOVARTIS PHARMA CANADA INC
NOVARTIS PHARMACEUTICALS CORP
NOVARTIS PHARMACEUTICALS CORP DBA GEIGY PHARMACEUTICALS DIV
NOVARTIS PHARMACEUTICALS CORP DBA SANDOZ PHARMACEUTICALS CORP
NOVARTIS PHARMACEUTICALS UK LTD
NOVEN PHARMACEUTICALS INC

NOVO NORDISK A/S
NOVO NORDISK PHARMACEUTICAL INDUSTRIES INC DBA NOVO NORDISK PHARMACEUTICALS INC
NOVOPHARM LTD
NYCOMED AMERSHAM PLC
NYCOMED INC
OMJ PHARMACEUTICALS INC
ONY INC
ORGANON INC
ORGANON IRELAND LTD
ORION CORP ORION PHARMA
ORTHO BIOTECH INC
ORTHO MCNEIL PHARMACEUTICAL INC
ORTHO PHARMACEUTICAL
OTSUKA PHARMACEUTICAL CO LTD
PAR PHARMACEUTICAL INC
PARKE DAVIS AND CO LTD
PARKE DAVIS DIV WARNER LAMBERT CO
PARKEDALE PHARMACEUTICALS INC
PFIZER CANADA INC
PFIZER LABORATORIES DIV PFIZER INC
PFIZER PHARMACEUTICALS INC
PHARMACHEMIE BV
PHARMACIA AND UPJOHN AB
PHARMACIA AND UPJOHN CO
PHARMACIA AND UPJOHN CO PHARMA DIV
PHARMACIA AND UPJOHN HILLEROD AS
PHARMACIA AND UPJOHN NV SA
PHARMACIA AND UPJOHN SPA
PHARMACIA PHARMACEUTICALS AB
PRATT PHARMACEUTICALS
PROCLINICAL INC
PROCTER AND GAMBLE DE MEXICO SA DE CV
PROCTER AND GAMBLE GMBH AND CO MANUFACTURING
PROCTER AND GAMBLE INC
PROCTER AND GAMBLE INTERAMERICAS INC
PROCTER AND GAMBLE MANUFACTURING CO
PROCTER AND GAMBLE PHARMACEUTICALS GERMANY GMBH
PROCTER AND GAMBLE PHARMACEUTICALS INC SUB PROCTER AND GAMBLE CO
PROCTER AND GAMBLE PHARMACEUTICALS PUERTO RICO INC
PURDUE FREDERICK CO
PUREPAC PHARMACEUTICAL CO DIV FAULDING INC
QUIMICA FARMACEUTICA BAYER SA
RHONE POULENC PROPHARM
RHONE POULENC RORER INC
RHONE POULENC RORER LTD
RHONE POULENC RORER PHARMACEUTICALS LTD
RHONE POULENC RORER PUERTO RICO INC
ROCHE DIAGNOSTICS GMBH
ROCHE PHARMA INC
ROCHE PRODUCTS INC
ROERIG
ROXANE LABORATORIES INC
ROYCE LABORATORIES DBA WATSON LABORATORIES INC
SANOFI PHARMACEUTICALS INC
SANOFI WINTHROP INDUSTRIE
SB PHARMCO PUERTO RICO INC
SCHEIN PHARMACEUTICAL INC
SCHERING AG
SCHERING CANADA INC
SCHERING CORP
SCHERING GMBH UND CO PRODUKTIONS KG
SCHERING PLOUGH PRODUCTS INC
SCHWARZ PHARMA INC
SEARLE CANADA INC
SEARLE DIV MONSANTO PLC
SEARLE LTD
SHIRE RICHWOOD INC
SIDMAK LABORATORIES INC
SIGMA TAU SPA
SMITHKLINE BEECHAM COSTA RICA SA
SMITHKLINE BEECHAM PHARMACEUTICALS CO
SMITHKLINE BEECHAM PLC
SOLOPAK MEDICAL PRODUCTS INC
SOLVAY PHARMACEUTICALS BV
SOLVAY PHARMACEUTICALS GMBH
SOLVAY PHARMACEUTICALS INC
SOMERSET PHARMACEUTICALS INC
STERIS LABORATORIES INC
SYNTEX FP INC
SYNTEX LABORATORIES INC SUB SYNTEX CORP
SYNTEX PUERTO RICO INC
TEVA PHARMACEUTICAL INDUSTRIES LTD
TEVA PHARMACEUTICAL INDUSTRIES LTD
TEVA PHARMACEUTICALS USA INC
UPSHER SMITH LABORATORIES INC
US BIOSCIENCE INC
VIVUS INC
WALLACE LABORATORIES DIV CARTER WALLACE INC
WARNER LAMBERT CO

WARRICK PHARMACEUTICALS CORP
WATSON LABORATORIES INC
WYETH LABORATORIES INC
WYETH PHARMACEUTICALS CO
YAMANOUCHI EUROPE BV
YAMANOUCHI PHARMACEUTICAL CO LTD
ZAMBON GROUP SPA

ZENECA GMBH
ZENECA PHARMACEUTICALS
ZENECA PHARMACEUTICALS DIV ZENECA INC
ZENECA SPA
ZENITH GOLDLINE PHARMACEUTICALS INC

Attachment C - June 22, 1999, memo to trade organizations

Date: June 22, 1999

From: Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

Subject: FDA's Y2K Survey

To: Trade Organization

As you are aware, we recently sent a Y2K assessment survey to help determine the Y2K readiness of the pharmaceutical industry. I appreciate all of the support that Trade Organization has given us on this initiative.

Starting next week, we will be contacting, via telephone, all prescription drug manufacturers that have not yet responded to our survey. I hope you will continue to support our efforts to obtain a high response rate. As you know, the information that we receive in response to this survey is extremely important because it will form the basis of the report that the agency provides to Congress and the American people on the Y2K readiness of the pharmaceutical industry.

Attached is a list of companies that are members or affiliates of Trade Organization that have not yet responded to our survey. At this time, I am asking you to provide your assistance in increasing our response rate by contacting those members who have not yet responded and encouraging them provide the requested information as soon as possible.

I know that as we work together on this issue, we will obtain the information we need to reassure the public that there will be an uninterrupted supply of safe and effective drug products. Consumer confidence in the preparedness of the pharmaceutical industry will, in turn, help decrease the likelihood of drug shortages due to stockpiling or consumer hoarding.

If you have any questions, please contact Khyati Roberts at robertsk@cder.fda.gov or 301-595-5470.

Thank you in advance for your assistance. I look forward to working with you and your colleagues in the future on this and other critical public health issues.

Janet Woodcock, M.D.

Attachment D - Telephone Interview Questions

Year 2000 Readiness Telephone Interview Script

Section 1 -Project Management – Master Project Plan

1-1. What definition of Y2K compliance did you use in your analysis?

1-2. Has a Year 2000 Master Project Plan been developed and approved?
When was, or will the plan be developed?
When was, or will, the plan be approved?
Who approved the plan (name and position)?

1-3. At what level does the plan have commitment within your organization?
Approval:
What is the highest level officer (or group of officers) which approved the plan. What are their titles and where are they in the organization?
Responsibility:
What is the highest level officer (or group) responsible for the implementation of the plan. What are their titles and where do they fit in the organization?

1-4. What does your Year 2000 Master Project Plan address?
Does the plan cover?
Buildings
Supply Chain
Computer Hardware and Software
Firmware
Interfaces
What else does the plan cover?

1-5. Is Year 2000 project status accurately reported to project sponsor, and other internal stakeholders?
What is the process for reporting Y2K status to the project sponsors and internal stakeholders?
Examples: Is there a periodic report to all customers? Is there an internal web page or shared database? Etc.

1-6. Are Year 2000 project status meetings held on a regular basis? How frequently?
Who is invited?

1-7. Is Year 2000 project manager documenting decisions and processes to support Y2K mitigation strategies and due diligence?
If so, how?
If not, what process is being used to document the work being performed?

1-8. Are official files maintained as part of your process?
If so, where are they stored? Are duplicates (paper, digital or microfiche) stored elsewhere?

1-9. Is there a formal Year 2000 Quality Assurance Plan?
Is it:
A specific Y2K plan
A modification of your standard QA plan
Or was the original QA plan used?

1-10. What does the QA Plan address?
Does it cover?
Documentation
Configuration Management
Contingency Planning
Testing
What else does it cover?

1-11. Was there an independent assessment?
If so, who performed it?
Was the independent party from inside or outside the company?
If not, what steps were taken to assure an objective viewpoint of the assessment?

1-12. Is there a documented Configuration Management Plan?
If so, is it:
A specific Y2K plan
A modification of your standard plan
Or was the original CM plan used?

1-13. Is there a Change Control process in place?
If so, is it:
A specific Y2K process
A modification of your standard process
Or was the original Change Control process used?

1-14. Is there an automated tool(s) used for source code version control?
What is the tool and who developed it?
What computer platforms did it support?

1-15. Is there an issue/trouble reporting/resolution tracking process in place?
Please briefly describe the process and the participants

Section 2 Inventory Collection Process (Inventory of items to be assessed, replaced or remediated)

2-1. Is the inventory collection process defined?
Is there a corporate-wide program or is there more than one?

2-2. Have the prioritization criteria been established?
What are those criteria?

2-3. What is the inventory collection status, milestone dates, % complete?
If it is not complete, when do you expect to complete it.

2.4. Do you have an inventory tracking system or documentation?
Where are the results maintained and tracked?

2-5. Have technology product/service suppliers been identified and inventoried?
What information is kept?
Is it on paper, on line and how do the internal users of these products and services access this information

2-6. What inventory validation technique is used?

2-7. What was the result of your inventory?
How many systems or tools had to be changed?

3-1. What procedures did your organization use to determine what to address in your Y2K assessment?
Who was involved?
What groups participated?
What was the final product (Report/Database, etc.)?

3-2. Did you work with your vendors to obtain vendor product readiness status?
What was the level of contact and cooperation?
Did they simply refer you to a web page or did they actively participate in your assessment?

3-3. What procedures were used for determining the vendor's readiness status?
Were Y2K web pages reviewed?
If so, did you retain copies of those pages?
Did you conduct specific tests on your own?
Did you analyze product specs?
Did you use another techniques?

3-4. What were the results of the vendor readiness assessment?
What vendor products were not compliant?
What impact, if any, does that have on the compliance of your products?

3-5. What are the expected horizon dates (date of first impact)?
Have any "horizon dates" already been encountered?
Were you ready in time?
Are there any upcoming horizon dates
Will you be ready?

3-6. Have your physical facilities been assessed for Y2K compliance?
How did you evaluate facility compliance?
What statements, web pages, etc were available to document the compliance status of facilities?
What assurances do you have from power companies, phone companies, etc.

3-7. What were the results of the physical facilities assessment?
Are there concerns about your ability to function through the Y2K window?

Section 4 –Remediation, Repair, Replace, Retire Phase

4-1. Are Remediation standards defined and documented?
Are these specific Y2K standards or have they been in use as part of your standard product development and maintenance methodology?

4-2. What Remediation process and methods are used?
Are automated code review tools used?
Do you have a tool to make, or suggest fixes to be made?

4-3. Are the standards being followed?
Do you have peer review standards?
What approvals are required for the implementation of a change?
If you use contractors for parts of the work, are, or were, they required to follow the same standards?
If not, what standards did they follow?

4-4. Have you had to take corrective action for any specific product? If so, for what product and what action was taken?

Section 5 –Year 2000 Application Testing

5-1. Is the Y2K testing approach, process and strategy documented (types of tests, techniques to be used, test participants)?
What groups participated in the definition of the process?

5-2. Have detailed test plans/directions been developed?
Who developed the plans?
Who approved the plans?
Were specific Y2K tests used or were normal test procedures deemed sufficient to cover the Y2K situation?

5-3. What Y2K critical dates were tested?
Did you test?
12/31/1999, 1/1/2000, 2/29/2000, 3/1/2000,2/29/2001
What other dates did you test?
What format is used to represent the data?

5-4. Have resource requirements been identified and allocated?
Were separate testbeds used?
What steps were taken to protect normal processes when clocks were reset for Y2K testing and returned to the actual date?

5-5. Has a detailed test schedule been established?
When was it established?
What was the schedule (general start – end dates)?
Was the schedule met?
How much is left to be done?
Do you expect to stay on schedule?

5-6. Has a trouble resolution procedure been defined? What does it include?

5-7. Have acceptance criteria been defined?
What groups defined them?
If not, how was the accuracy of the results determined or documented?

5-8. What were your test results?

5-9. Have the test results been archived for future reference?
Have any printouts, etc been saved in either paper or digital form?
Have audit/reviewer annotations been saved to allow confirmation of the review?
Have test inputs been saved so that the test can be repeated?

Section 6 – Integration Testing

6-1. Are internal and external system interfaces understood and coordinated?
- Internal interfaces are interfaces completely inside the company
- External interfaces involve entities outside of the company.
- Includes both inputs and outputs.

How was the analysis done?
Are the interfaces documented?

6-2. Has your supply chain been verified for Y2K compliance?
Has there been a test with the supply chain?
If not, what verification process was used?

6-3. What were the results of your supply chain test?

6-4. Are Test Reports and data available for review?

6-5. Are all the applications undergoing Y2K testing in production?

6-6. How did you accept and certify the Y2K integration test?
Who developed the test?
Who performed the test?
Who validated the test?
Was there a review or audit of the test by a third party?

Section 7 –Contingency Planning

7-1. Are the business unit manager(s) aware of year 2000 risks and issues?
How were they made aware?
How have you verified that they understand the problem and the potential impact in their areas of responsibility?
Are there meetings, etc.?

7-2. Have business units examined key business processes for year 2000 risks and potential implications?

7-3. Has a risk inventory been compiled?
Who compiled it?
Were the results documented?

7-4. If you know that you will have problems with Y2K, what work-arounds have you put into place?
For each problem,
What was the problem?
What is the potential impact?
What is the work-around?

7-5. Have you established Contingency plans in the event something unexpected goes wrong? If so, what does the plan address and what is the actual plan?
Who has authority to declare a problem?
Are there plans to rapidly bring in resources?

7-6. What steps have you taken to ensure that you will have adequate bulk material on hand from ***foreign suppliers*** to compensate for any potential manufacturing disruptions due to Y2K problems?

7-7 Has the contingency plan been tested?

7-8 How was the contingency plan validated?

Attachment E - Survey Results

Table E1 - Summary of Responses For All Categories
As of October 15, 1999

Responses	RX	OT	BU	DI	GA	Total
1. Response as Subsidiary	212	20	89	46	47	**414**
	19.8%	4.2%	7.2%	11.7%	4.4%	**9.8%**
2. Surveys Completed (via mail or phone)	630	311	438	232	796	**2407**
	58.9%	65.6%	35.5%	59.2%	75.2%	**56.9%**
Yes to Q1	461	254	322	187	717	**1941**
N/A to Q1	5	5	3	5	15	**33**
Missing info on Q1	0	1	1	0	3	**5**
No to Q1	164	51	112	40	61	**428**
Steps by 6/99	14	1	9	2	2	28
Steps by 7/99	8	2	8	1	2	21
Steps by 8/99	14	2	10	2	2	30
Steps by 9/99	49	23	49	10	16	147
Steps by 10/99	44	11	22	13	15	105
Steps by 11/99	16	1	6	4	9	36
Steps by 12/99	14	4	4	4	5	35
Steps by 2/01	0	0	0	1	0	1
Steps by 2/02	0	1	0	0	0	1
No date	5	6	4	3	10	28
3. Form Letter Received	20	9	34	10	31	**104**
	1.9%	1.9%	2.8%	2.6%	2.9%	**2.5%**
4. Returned In Mail	2	30	182	27	22	**263**
	0.2%	6.3%	14.8%	6.9%	2.1%	**6.2%**
5. Out of Business	192	8	10	6	7	**223**
	17.9%	1.7%	0.8%	1.5%	0.7%	**5.3%**
6. No Response	14	96	480	71	156	**817**
	1.3%	20.3%	38.9%	18.1%	14.7%	**19.3%**
TOTAL	**1070**	**474**	**1233**	**392**	**1059**	**4228**
COMPLETION RATE	1054	348	571	294	881	**3148**
(Subsidiary + Surveys + FLs + Out of Business)	98.5%	73.4%	46.3%	75.0%	83.2%	**74.5%**

Table E2 - Summary of Foreign Countries

As of October 15, 1999

Responses	Asia & Africa	Far East	Eastern Europe	Western Europe	South & Central America	North America & Others	Total
1. Response as Subsidiary	19	11	0	110	10	25	**175**
	7.1%	2.1%	0.0%	16.3%	10.0%	14.4%	**9.9%**
2. Surveys Completed (via mail or phone)	76	169	17	306	39	92	**699**
	28.3%	32.8%	45.9%	45.3%	39.0%	52.9%	**39.4%**
Yes to Q1	61	117	10	221	30	78	**517**
N/A to Q1	3	1					**4**
Missing info on Q1				1			**1**
No to Q1	12	51	7	84	9	14	**177**
Steps by 6/99	1	3	0	7	0	3	14
Steps by 7/99	2	5	0	3	1	1	12
Steps by 8/99	1	4	0	7	1	1	14
Steps by 9/99	5	23	4	31	0	1	64
Steps by 10/99	1	7	3	22	6	5	44
Steps by 11/99	0	2	0	8	0	2	12
Steps by 12/99	0	1	0	6	1	0	8
No date	0	5	0	0	0	1	6
3. Form Letter Received	7	6	1	35	1	10	**60**
	2.6%	1.2%	2.7%	5.2%	1.0%	5.7%	**3.4%**
4. Returned In Mail	14	64	3	79	13	11	**184**
	5.2%	12.4%	8.1%	11.7%	13.0%	6.3%	**10.4%**
5. Out of Business	22	59	4	59	16	22	**182**
	8.2%	11.4%	10.8%	8.7%	16.0%	12.6%	**10.3%**
6. No Response	131	207	12	87	21	14	**472**
	48.7%	40.1%	32.4%	12.9%	21.0%	8.0%	**26.6%**
TOTAL	**269**	**516**	**37**	**676**	**100**	**174**	**1775**
COMPLETION RATE	124	245	22	510	66	127	**1116**
Subsidiary + Surveys + FLs + Out of Business	46.1%	47.5%	59.5%	75.4%	66.0%	73.0%	**62.9%**

Table E3 - Summary of Responses to Questions 2-6

As of October 15, 1999

2. Do you plan on having an independent organization (i.e., a group other than the one who did the initial analysis) conduct a review of your Y2K program?

Responses	RX	OT	BU	DI	GA	Total
Yes	207	71	160	52	117	**607**
No	411	229	265	167	648	**1723**
N/A	5	4	2	5	12	**28**
Missing	4	7	11	8	17	**47**
Don't Know					2	**2**

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

Yes	482	116	352	69	40	**1059**
No	136	180	69	143	713	**1241**
N/A	4	4	3	9	16	**36**
Missing	6	11	14	11	25	**67**
Don't Know	2				2	**4**

3a. Have you asked these foreign suppliers of their Y2K readiness?

Yes	396	94	275	59	35	**859**
No	84	22	75	10	5	**196**
N/A			1			**1**
Missing	1		1			**2**
Don't Know	1					**1**

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	402	235	273	161	588	**1659**
Refused	1					**1**
No	209	63	156	51	124	**603**
N/A	12	7	4	13	58	**94**
Missing	6	6	5	7	25	**49**
Don't Know					1	**1**

4a. Where appropriate, have the components of the contingency plans been tested?

Yes	268	174	188	115	441	**1186**
No	119	48	71	33	108	**379**
N/A	6	7	7	2	15	**37**
Missing	10	6	9	11	23	**59**
Don't Know					1	**1**

4b. Do the contingency plans address potential problems with your key business partners (suppliers, vendors, distributors & others)?

Yes	455	239	308	146	583	**1731**
No	78	27	73	29	65	**272**
N/A	34	22	19	24	78	**177**
Missing	62	23	38	33	69	**225**
Don't Know	1				1	**2**

4c. Do your contingency plans address potential problems with foreign suppliers (e.g., establishment of alternate suppliers of materials)?

Yes	365	115	256	67	94	**897**
Refused	1					**1**
No	134	82	98	62	300	**676**
N/A	65	86	39	71	317	**578**
Missing	64	28	44	32	85	**253**
Don't Know	1		1			**2**

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

Yes	291	95	196	79	234	**895**
No	315	197	223	121	463	**1319**
N/A	15	6	6	15	65	**107**
Missing	7	13	13	17	34	**84**
Don't Know	2					**2**

5a. If you face an 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	477	225	309	152	431	**1594**
No	73	35	78	27	168	**381**
N/A	18	11	7	17	83	**136**
Missing	60	40	44	36	114	**294**
Don't Know	2					**2**

6. Do you anticipate submitting supplements to address any Y2K manufacturing changes?

Yes	38	11	40	10	24	**123**
Refused					1	**1**
No	386	149	229	103	289	**1156**
N/A	189	138	149	103	446	**1025**
Missing	16	13	20	16	36	**101**
Don't Know	1					**1**

Attachment F - Audit Results

Table F1 - Summary of Audit Results

As of October 15, 1999

	Priority	Non Priority	Total
Green	**123**	**12**	**135**
via Telephone	106	1	107
via Site Visit	17	11	28
Green w/Caution	**8**	**1**	**9**
via Telephone	5		5
via Site Visit	3	1	4
Watch	**0**	**1**	**1**
via Telephone			0
via Site Visit		1	1
Yellow	**1**	**0**	**1**
via Telephone	1		1
via Site Visit			0
Red	**0**	**0**	**0**
via Telephone			0
via Site Visit			0
Completed - Not Rated	**8**	**2**	**10**
via Telephone	8		8
via Site Visit		2	2
Scheduled	**5**	**1**	**6**
via Telephone	5		5
via Site Visit		1	1
Refused	**2**	**4**	**6**
via Telephone	2	2	4
via Site Visit		2	2
Remaining to be Scheduled	**14**	**1**	**15**
via Telephone	14		14
via Site Visit	0	1	1
Total	**161**	**22**	**183**

Green: Item on track, issues known & appropriate actions planned (with Caution: Minor Issues)
Watch: Potential major issues (no known problems, but there may be trouble lurking)
Yellow: Critical issue impacting success (trouble identified)
Red: Item is behind, out of control, or well over budget (serious difficulty that will likely prohibit success)

Attachment G - Contingency Plans