Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FDA'S URGENT NOTICE

JUNE GIBBS BROWN
Inspector General

JULY 1996
OEI-07-94-00631

OFFICE OF INSPECTOR GENERAL

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This report was prepared in the Kansas City Regional Office under the direction of James H. Wolf, Regional Inspector General. Project staff:

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PURPOSE

The purpose of this inspection was to assess the effectiveness of the Food and Drug Administration's (FDA) Urgent Notice on recalled blood glucose test strips, released to retail pharmacies October 11, 1995.

RECALL AND URGENT NOTICE OF DEFECTIVE TEST STRIPS

The FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating devices and radiological health which includes identifying and addressing postmarket safety questions that arise. In dealing with these issues, FDA will occasionally notify members of the health care community to inform them of the problem and to provide important follow up instructions to prevent further recurrence.

In January 1995, a manufacturer of blood glucose test strips voluntarily recalled certain lots of test strips and in June 1995 extended the voluntary recall to include all lots current in the marketplace. Patients with diabetes make use of the strips in monitors to measure their blood glucose levels and, if necessary, adjust insulin doses. Following the extended recall in June 1995, the FDA found that recalled test strips were still on pharmacy shelves and available to the public. The FDA took a number of actions, including mailing an Urgent Notice to all pharmacies in the U.S. on October 11, 1995. The notice was developed in collaboration with the manufacturer and consequently reflects wording negotiated between FDA and the manufacturer. The notice described the test strip problem and requested all pharmacies to remove any affected stock and post an important public notice for consumers who may have purchased these products previously.

While CDRH was in the process of issuing the Urgent Notice, it requested us to closely monitor the receipt of the notice and assess its effectiveness. We conducted a nationally representative telephone survey of 279 pharmacies to get a broad perspective of how pharmacies perceived the Urgent Notice and a multi-regional on-site survey of 183 pharmacies to validate national information and to make a personal examination of their test strip stock. A more detailed description of the methodology is found in Attachment A.

FINDINGS

A majority of the pharmacists surveyed acknowledged receiving the FDA "Urgent Notice About Recalled Blood Glucose Test Strips." One-third or more did not.

Our study revealed that 67 percent of the pharmacists telephoned and 56 percent of those visited acknowledged receiving the Urgent Notice.

Discussion. We are unable to explain why some pharmacists did not know about the notice. We specifically asked to talk to the head pharmacist or other person who should have been made aware of an important FDA notice. One possibility is that the mail was forwarded to another department in the store or the store manager. However, we have no data to document the prevalence of this practice.

Other possible explanations are that respondents had not yet received the FDA notice at the time we conducted our surveys, or had received it but forgotten about it. Both of these were minimized by our study design. We waited 10 days after FDA had mailed the notice before we began our surveys, and completed them within a two week period.

Another possible explanation is that the mailing list we used was different from the one used by FDA. The FDA obtained its list from a marketing firm that used the mailing list of the National Council for Prescription Drug Programs. We did not use this same list for two reasons. Various logistical factors, including lack of computerized format, precluded our using this list in a timely fashion, which was critical for the evaluation. Second, the list we used from the controlled substances registrant file of pharmacies maintained by the Drug Enforcement Administration was readily available in usable format. While neither we nor FDA believed the lists to be identical, they both represent licensed pharmacies and should be very similar. We were unable to make a detailed comparison of the lists for this study.

Clearly, more research would be needed to determine exactly why some of the pharmacists we interviewed did not acknowledge receipt of the notice.

The FDA Urgent Notice was the vehicle that made approximately one-half of the pharmacies that received it aware of the blood glucose test strip problem.

Of the pharmacists that acknowledged receipt, 45 percent of the pharmacists telephoned and 58 percent of the pharmacists visited learned of the recalled glucose strips from the Urgent Notice.

Of the remaining pharmacists that did not receive the notice, only 35 percent of those surveyed by telephone and 40 percent of those visited said they were previously aware of the problem.

While a majority of pharmacists reported checking for and removing affected stock, we found recalled blood glucose strips in one pharmacy we visited.

The FDA recommended that pharmacies check their inventories and immediately remove any identified lot numbers from their shelves. We asked those pharmacists who had acknowledged receiving the alert if they carried out this recommendation; 84 percent of those telephoned and 71 percent of those visited reported they had in fact checked for and removed any recalled stock. The only reason they stated for not following this recommendation was not carrying the affected brands.

In all our site visits, regardless of whether the pharmacist acknowledged receipt of the notice, we attempted to verify that affected stock was not available for sale. We were unable to examine stock in all locations, and some pharmacies did not carry the affected brands. We did find one pharmacy with four boxes of recalled test strips on their shelf, which were promptly removed when brought to their attention.

Discussion. Based on the first two findings alone one might have expected to find more instances of recalled product on the shelves. After all, most of those who had not received the FDA notice were not previously aware of the problem.

One possible explanation is that recalled stock may already have been sold. The manufacturer sent out its first recall notice in January 1995, a full 9 months before FDA sent out its Urgent Notice. Presumably, the distributors would have ceased shipping the defective stock as soon as they received the manufacturer's recall notice. During the ensuing 9 months, any pharmacies that were not notified of the defective product may well have depleted their stock through sales.

Another possible explanation is the fact that the pharmacies carrying this brand of product are not randomly distributed across the country like our phone sample was nor concentrated in the nine metropolitan areas where we conducted our on-site reviews. It may be that the manufacturer's recall effectively reached most of the pharmacies which carry the brand. However, we must caution that this is pure speculation on our part. Our study was not designed to test the effectiveness of the manufacturer's recall.

Few pharmacies posted the public notice which FDA had provided.

The FDA also recommended that pharmacies post an attached important public notice about the defective test strips where it would be visible to consumers. We found that, of the pharmacies receiving the Urgent Notice, only 29 percent of the telephoned pharmacies and 13 percent of the visited pharmacies posted the public notice. The pharmacies not posting the notice gave the primary reasons as the brands were not stocked, they did not realize they were supposed to post the public notice, and they did not read the Urgent Notice thoroughly enough to realize there was an attached notice. Comments offered by some of the pharmacists indicated that they did not understand the importance of posting the notice. They suggested that FDA: more clearly indicate the importance of posting it; highlight the existence of the public notice clearly at the front of the Urgent Notice; and clarify whether it is necessary to post a notice regarding a product that is not stocked.

ISSUES FOR CONSIDERATION

Our study leaves several issues unanswered. FDA's urgent notice did reach many pharmacists that would not have otherwise been aware of the defective product. Why it did not reach the others is not evident from our study. Clearly, more research on how to effectively reach this kind of audience is warranted.

We were pleased to be of assistance to FDA in its efforts to improve the urgent notification process. We strongly encourage CDRH to continue in its efforts to improve notification of the health care community on important safety issues with medical devices. Based on our review of this single Urgent Notice, we offer the following issues for consideration as CDRH explores other dissemination methods and evaluates possible changes in format for notices and alerts. We recognize the budgetary constraints that exist in piloting or implementing any new options. As the responsibility of communicating safety information to the health care community is shared with other Centers, cooperation and more focused attention by several Centers may yield the best results.

The FDA should consider other dissemination methods for urgent alert information, especially for those situations where complete dissemination is essential.

The process of using first class mail was not successful in reaching the entire target audience for this Urgent Notice. The success of any dissemination through mail will be highly dependent on several variables, such as the accuracy of the mailing list and internal mail distribution within businesses or offices. No doubt, situations will continue to arise where first class mail may be the only option available. Also, as a more "official" document of the agency, with emblems and signatures, first class mail may always be useful as a follow up to other dissemination vehicles. However, where timeliness or complete dissemination is essential, other methods may provide more reliable, efficient means. These methods might include telephone, fax, or electronic means, such as on-line systems used by claims processors or third party programs. Health care professional groups and associations may be helpful in identifying or creating networks for facilitating dissemination.

The FDA should consider reformatting future alerts and notices to clarify the actions health care professionals are recommended to carry out.

Not all those who said they had received the notice carried out the recommendation to post the consumer notice. Comments from our survey indicated that some did not see the instructions, perhaps not reading the notice completely, while others exercised judgment and determined that it was not necessary. For future alerts, clearly stated recommended actions may need to be highlighted or prominently placed to focus reader attention. These issues of clarity and format will also be relevant if other dissemination vehicles are adopted.

AGENCY COMMENTS AND OIG RESPONSE

We received comments from FDA on the draft report and they are included as Attachment B. They were generally supportive of the evaluation and results, and have agreed to undertake a broader review of the program, including an in-depth look at new technologies for communication. The FDA did disagree with our conclusion in the draft report that first class mail could not be relied upon to reach all pharmacies. We agree that this conclusion was stated too broadly. We did not measure whether

the notice was delivered to pharmacies, but rather examined whether the responsible pharmacist was aware of the information that had been mailed. We modified our report to clarify that our conclusion related to the pharmacists, not the pharmacies.

The FDA also provided a number of helpful technical comments, and we have made changes where appropriate. The FDA also asked us for any specific recommendations we might have on reformatting the urgent notices to make them more effective. While we have our opinions on the matter, we feel that it would be best if any changes in reformatting notices should be considered as part of a broader strategy and developed by professionals knowledgeable in the communications field. At FDA's suggestion, we have included copies of the Urgent Notice (Attachment C) and survey instruments (Attachments D and E).

METHODOLOGY

We held several discussions with representatives of the CDRH to determine the focus of the study. We decided to assess the Urgent Notice by conducting two surveys of community pharmacies in the United States. Two separate samples were drawn for the surveys. The first sample was intended to be representative of all pharmacies in the country. This sample was used for the national telephone survey to assess the effectiveness of the FDA urgent notice by obtaining a broad perspective of how both urban and rural pharmacies throughout the country perceived the Urgent Notice. The second sample included only pharmacies located in specified urban areas. This was used for the second survey, which was a regional on-site survey, to validate national information solicited and to make a personal examination of their blood glucose test strip stock.

To develop our sampling frame of pharmacies in the United States, we obtained the Controlled Substances Registrant File of pharmacies maintained by the Drug Enforcement Administration, Department of Justice. This file contained the names and addresses of 60,970 registered pharmacies with a business activity code of 'A', indicating the entity was a pharmacy. This was the only source we used to obtain sample pharmacies for data collection.

National Telephone Survey

This survey involved contacting, by telephone, a simple random sample of 330 retail pharmacies from the list of 60,970. Based upon our sampling assumptions, this sample size would give us a 90 percent assurance that the true proportion of pharmacies recognizing the Urgent Notice would be within five percent of our estimate.

The actual number of pharmacies completing the telephone survey was 279 or 85 percent. There are various reasons why some pharmacies did not complete the survey which included (1) no longer in business, (2) non-cooperation by the pharmacist, and (3) the business was not a retail pharmacy.

Regional On-site Survey

Using simple random sampling, we selected 25 pharmacies in each of the following metropolitan areas; Boston, New York, Philadelphia, Atlanta, Kansas City, Chicago, Dallas, San Francisco, and Washington D.C., for a total of 225 pharmacies. This sample size was dictated by resource constraints rather than desired precision levels. Any pharmacies selected in the national sample that fell within the sampling frame of any of the nine metropolitan areas was automatically included in the regional sample.

Of the 225 pharmacies in the sample, the actual number of pharmacies visited and completing the on-site survey was 183 or 81 percent. Among the reasons for not completing all the on-site visits were (1) pharmacy no longer in business, (2) business was not a retail pharmacy, and (3) pharmacy location was outside the area to be visited.

Both surveys were conducted during a two week period starting 10 days after FDA sent out its Urgent Notice.

The questions used in both survey documents were identical. However, the on-site visits included examining the pharmacies' test strip inventory for the brands listed in the Urgent Notice and any identified lot numbers.

The following table provides our estimates of the standard errors and lower and upper 95 percent confidence intervals for figures presented in this report. Estimates for the local site visits are appropriately weighted to reflect the sampling design. Only in the case of posting the notice does there appear to be a significant difference in the proportions. Of those acknowledging receiving the Urgent Notice, 29 percent of those contacted by telephone claim to have posted the notice. Less than half of that proportion made a similar claim among the local site visits, 13 percent. The confidence intervals of these two estimates do not overlap.

Estimates, Standard Errors and Confidence Intervals
for Values Presented in Report

			95% Conf. Interval	
	Est.	Std. Err.	Lower	Upper
Proportion of Pharmacies Receiving Urgent Notice				
Telephone Survey	0.667	0.028	0.612	0.722
Local Visit Survey	0.561	0.044	0.475	0.647
Proportion Learning of Recall from Urgent Notice*				
Telephone Survey	0.452	0.036	0.381	0.523
Local Visit Survey	0.579	0.060	0.461	0.697
Proportion Posting Urgent Notice*				
Telephone Survey	0.290	0.033	0.225	0.355
Local Visit Survey	0.130	0.039	0.054	0.206

*Among Those Acknowledging Receipt

We conducted our review in accordance with the ***Quality Standards for Inspections*** issued by the President's Council on Integrity and Efficiency.

Attachment B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date MAY 31 1996

From

Deputy Commissioner for Management and Systems (Acting)

Subject Food and Drug Administration's (FDA) Comments on the Office of Inspector General's (OIG) Draft Report, "FDA's Urgent Notice, " (OEI-07-94-00631) - INFORMATION

To

Deputy Inspector General for Evaluation and Inspections

We reviewed the referenced draft report and prepared the attached comments.

We are pleased to report that FDA's Deputy Commissioner for Operations has agreed to conduct a review of your report's suggestions.

If your staff has any questions, please have them contact Jim Dillon on (301) 443-6392.

Robert J. Byrd

Attachment

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT, "FDA'S URGENT NOTICE," OEI-07-94-00631, APRIL 9, 1996

General Comments

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the draft report. We acknowledge the OIG's prompt response and thoughtful efforts to our request to evaluate the effectiveness of the Agency's October 11, 1995 Urgent Notice on recalled blood glucose test strips. We believe the report will provide useful information to improve the Agency's Center for Devices and Radiological Health's (CDRH) Postmarket Safety Notification Program.

The FDA agrees with the OIG draft report that recognizes the tremendous importance of rapidly and accurately communicating safety information to the health care community. The FDA also agrees that we must assure that our outreach capabilities are of the highest quality and are received by the health care community in a format that is maximumly useful. The OIG draft report serves as a timely catalyst for encouraging FDA to undertake a broader examination and to improve the overall program. To this end, the Deputy Commissioner for Operations has agreed to conduct a prompt review of the OIG suggestions, including an in-depth look at new technology (such as electronic communications) and new approaches to older technology (such as reformatting existing alerts and notices).

The FDA disagrees with the OIG's conclusion that states FDA's process of using first class mail cannot be relied upon to reach all pharmacies. This conclusion is based on the OIG's finding that one-third or more of the pharmacies surveyed did not acknowledge receiving the "urgent notice." This finding is incongruent with FDA's rate of returned notices. Of the approximately 66,000 urgent notices sent to pharmacies, fewer than 1,000 were returned to FDA resulting in a return rate of 1.5%. In addition, OIG gave FDA a list of names and addresses of the pharmacists who stated they did not receive the notice so that we could reissue it. The Agency did not receive any returned notices after they reissued them. As discussed in our technical comments, we asked OIG to provide more explanations concerning the issues addressing the acknowledgment of notices. Since there are many unanswered issues, we believe more research is needed before drawing a conclusion concerning the use of first class mail.

HFZ-510
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FIRST CLASS MAIL
POSTAGE AND FEES PAID
PHS/FDA
PERMIT NO. G-285

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FDA IMPORTANT NOTICE:
For Users of Blood Glucose Test Strips
(Please post the enclosed Notice page)

FDA IMPORTANT NOTICE

For Users of Blood Glucose Test Strips

IMPORTANT NOTICE
FOR USERS OF
BLOOD GLUCOSE TEST STRIPS

WHAT'S THE PROBLEM?

Some brands of blood glucose test strips for use in blood glucose meters may give incorrect high or low readings, leading to **serious health problems**. The manufacturer has recalled the product and asked that these strips be taken off the store shelves, but some people may still be using the recalled strips.

HOW DO I KNOW IF I HAVE THE RECALLED TEST STRIPS?

You must look at two things:

1. **Check the brand**. The following brands were recalled:

BRITE- LIFE	HEALTH MART	QUICK CHECK ONE
BROOKS	LONGS	QUICK CHECK 3
BROOKS 1	MK (MEDICAL)	RELIEF PLUS
FAMILY PHARMACY	PERRY 1	RELIEF PLUS ONE
FULL VALUE	PERRY HEALTH CARE	TOP CARE
GIANT EAGLE	QUALITEST 3	VALU-RITE
GOOD NEIGHBOR		

2. **Check the lot number on the container**. The recalled strips have lot numbers beginning with **30, 31, 41, or 43**. These brands are OK if they have other lot numbers.

IF YOU ARE USING BLOOD GLUCOSE TEST STRIPS THAT MATCH THE ABOVE BRANDS AND LOT NUMBERS:

1. **Stop using these test strips** and purchase a fresh supply.

2. Continue using your blood glucose meter with your new test strips and follow your doctor's instructions.

3. Contact your pharmacist or doctor if you have concerns or questions.

4. For information on how to exchange recalled test strips, call the manufacturer at 1-800- 446-4374 from 8:00 a.m. to 4:00 p.m. Pacific Time and 11:00 a.m. to 7:00 p.m. Eastern Time.

Diagnostic Solutions, Inc. has improved the manufacturing process to correct the problem and the company is now manufacturing new strips under these same brand names. The new strips are sold in containers that look almost identical to those in which the recalled test strips are packaged. Therefore, to identify the recalled test strips, it is important to **examine the lot numbers**.

OTHER RECOMMENDED ACTIONS

In the interest of safety to patients, who may still have the recalled strips in their homes, FDA and the manufacturer are also asking that:

- **Health care facilities** stop use of the recalled strips
- **Health care professionals** display and disseminate the attached Important Notice and advise patients to discontinue use of the recalled test strips, and
- **Organizations** notify their members. (This document and the attached Important Notice may be reproduced.)

In the meantime, FDA will continue to monitor the effectiveness of the recall. It is critical that all pharmacies complete the recall process that the company has initiated by following the above recommendations.

Diagnostic Solutions, Inc., will replace the recalled test strips. For more information, call 1-800-446-4374. This number is available to health care professionals and consumers. The hours of operation are 8:00 a.m. to 4:00 p.m. Pacific Time/11:00 a.m. to 7:00 p.m. Eastern Time.

Sincerely yours,

D. Bruce Burlington
Director
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 11, 1995

URGENT NOTICE ABOUT RECALLED BLOOD GLUCOSE TEST STRIPS

Dear Health Care Professionals:

A number of blood glucose test strips were recently recalled by the manufacturer because they may give inaccurate readings, both high and low, posing a **potentially serious health risk to users**.

The strips were recalled and a press release issued by the manufacturer. However, FDA and the manufacturer have recently found recalled strips in some retail outlets and health care facilities, such as nursing homes. The recalled test strips may also be in home medicine cabinets.

Retailers are hereby notified by FDA in conjunction with Diagnostic Solutions, Inc., that notifications concerning recalled blood glucose test strips should not be ignored.

RECOMMENDED ACTIONS

FDA and the manufacturer are **urging** that pharmacies and health care facilities:

- check inventories and immediately remove the indicated test strips from their shelves, and
- post the attached Important Notice where it is visible to consumers.

HOW TO IDENTIFY THE PROBLEM TEST STRIPS

The recalled test strips, all manufactured by Diagnostic Solutions, Inc., were sold under nineteen brand names, as listed below. All the recalled test strips have lot numbers beginning with **30, 31, 41, or 43** and expiration dates ranging from February 1993 to December 1996. **Other lot numbers of these brands are not affected.**

Brand Names

BRITE- LIFE	HEALTH MART	QUICK CHECK ONE
BROOKS	LONGS	QUICK CHECK 3
BROOKS 1	MK (MEDICAL)	RELIEF PLUS
FAMILY PHARMACY	PERRY 1	RELIEF PLUS ONE
FULL VALUE	PERRY HEALTH CARE	TOP CARE
GIANT EAGLE	QUALITEST 3	VALU-RITE
GOOD NEIGHBOR		

Attachment D

Office of Inspector General
Office of Evaluation and Inspections
Kansas City Regional Office

TELEPHONE SURVEY DOCUMENT

FDA's URGENT NOTICE PROCESS
INSPECTION #OEI-07-94-00631

Pharmacy Name _____ Date _____

Pharmacy Address _____ Phone#_____

_____

Respondent/Pharmacist Name _____

NOTE: You will need to determine if the pharmacist on duty will be able to answer the questions. The senior pharmacist or pharmacist-manager would be preferable; at a minimum, you should speak with a full-time (or close to full-time) pharmacist who regularly works in that pharmacy. Pharmacists who work part-time (or p.r.n. or on-call basis) or in several pharmacies will probably not be the best source of information. If the only pharmacist available is in this latter category, ask when the senior pharmacist will be available and call back.

1. Did you receive the Urgent Notice about Recalled Blood Glucose Strips issued by FDA on October 11, 1995 (the title was in bold red letters)?

   Yes _____ No _____

   If no, explain to them that you will advise FDA so it can mail them the Urgent Notice.

2. Were you previously aware of the problem with these glucose strips?

   Yes _____ No _____

   If yes, when and how did you learn of the problem?

NOTE: IF RESPONDENT DID NOT RECEIVE THE URGENT NOTICE END THE INTERVIEW AT THIS POINT.

3. Did you follow the recommendation in FDA's Notice checking your inventory and immediately removing the indicated test strips?

Yes _____ No _____

If no, why not?

4. Did you post the attached important Notice where it was visible to consumers?

Yes _____ No _____

If yes, describe where the Notice was posted.

If no, why didn't you post the important Notice?

5. Have you disseminated the important Notice and/or advised individuals to discontinue use of the recalled test strips?

Yes _____ No _____

If yes, to whom?

6. Did the Notice raise questions or concerns which required you to contact FDA?

Yes _____ No _____

If yes, what were those questions/concerns?

7. Did you think the Urgent Notice was clearly and understandably written?

Yes _____ No _____

If no, what particular portion of the Notice caused you problems?

8. Do you have any additional comments or suggestions that could improve future FDA Notices?

Yes _____ No _____

If yes, please explain.

Attachment E

Office of Inspector General
Office of Evaluation and Inspections

ON-SITE SURVEY DOCUMENT

FDA's URGENT NOTICE PROCESS
INSPECTION #OEI-07-94-00631

Pharmacy Name _____ Date _____

Pharmacy Address _____ Phone#_____

_____

Respondent/Pharmacist Name _____

Upon entering the pharmacy, ask to see the head pharmacist.

NOTE: You will need to determine if the pharmacist on duty will be able to answer the questions. The senior pharmacist or pharmacist-manager would be preferable; at a minimum, you should speak with a full-time (or close to full-time) pharmacist who regularly works in that pharmacy. Pharmacists who work part-time (or p.r.n. or on-call basis) or in several pharmacies will probably not be the best source of information. If the only pharmacist available is in this latter category, ask when the senior pharmacist will be available and do a revisit.

1. Did you receive the Urgent Notice about Recalled Blood Glucose Strips issued by FDA on October 11, 1995?

   Yes _____ No _____

   NOTE: If they did not receive the Urgent Notice provide them with a copy of the Urgent Notice and the attached notice to be posted for their review.

   If the pharmacy is located in a "store," ask if it is possible that the "store" manager received the Urgent Notice in the mail and it didn't get to the pharmacy? If the pharmacist believes this is a strong possibility, ask the "store" manager if he/she did get the notice.

2. Were you previously aware of the problem with the blood glucose strips?

   Yes _____ No _____

   If yes, when and how did you learn of the problem?

7. Did you think the Urgent Notice was clearly and understandably written?

Yes _____ No _____

If no, what particular portion of the Notice caused you problems?

8. Do you have any additional comments or suggestions that could improve future FDA Notices?

Yes _____ No _____

If yes, please explain.