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AN ECONOMIC STUDY OF THE NEW TAMPER-RESISTANT PACKAGING REGULATION

By

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ABSTRACT

AN ECONOMIC STUDY OF THE NEW TAMPER-RESISTANT PACKAGING REGULATION

By

Valerie Hamm

In November 1982, the FDA issued a regulation requiring tamper-resistant packaging for all over-the-counter (O-T-C) drug products for retail sale. This sudden legislation resulted in many economic problems for all involved. These economic effects were studied through the use of a mail-in survey which gathered specific economic information from both tamper-resistant packaging supplier companies and tamper-resistant packaging user companies.

The companies required to use tamper-resistant packaging experienced many new costs due to the new regulation. Their total cost increase per package, however, was quite a bit lower than the actual price increases their customers are now paying for the company's products.

The tamper-resistant supplier companies also experienced many additional costs due to the tamper-resistant regulation. Their total costs seem to be lower than the dollar value of their increased sales from tamper-resistant materials or machinery. Even though their gains outweigh their costs from this regulation, the suppliers indicate they will pass their costs on to their consumers.

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INTRODUCTION

Between September 30, 1982, and October 2, 1982, seven people died in the Chicago, Illinois, area from cyanide poisoning. It appears that the person(s) responsible for the deaths replaced the ingredients in Extra Strength Tylenol Capsules with the poison and put a few contaminated capsules in each of eight containers. They then replaced them on the shelves at the front of retail displays where they were quickly purchased. The victims, having no indication that the product had been tampered with, consumed the medication and died.

In order to protect the public from further product tampering crimes, State and local governments proposed various laws and regulations concerning the packaging of over-the-counter drug products. Cook County, Illinois, approved an ordinance in early October requiring that all O-T-C drugs sold in that county be in sealed containers.[1] The city of Chicago also proposed a similar ordinance.[2]

In order to assure uniform guidelines for all manufacturers of O-T-C drugs in all geographic markets, the FDA decided to develop and issue a regulation at the national level to protect the public from the possibility of O-T-C product tampering. The government realizes that they can not

guarantee that products will be tamper-proof, but they feel certain it is possible to make them "more resistant to tampering."[3]

This new FDA regulation will preempt the various State and local packaging requirements that have been issued.[4]

HISTORY OF TAMPER-RESISTANT PACKAGING

Tamper-resistant packaging has been available since the early 1900's. It is most commonly used as a device to reduce pilferage, consumer product sampling, and cap switching which is done to take advantage of lower prices. It has been required for certain products, but the reason for this was to insure product sterility or quality such as with opthalmics,[5] milk[6] and liquor.[7] Tamper-resistant packaging has not yet been used to prevent a determined individual from getting to the product without alerting the purchaser.

THE NEW REGULATION: 21 CFR PARTS 211, 314 and 700

The new regulation amends Title 21 of the Code of Federal Regulations and its following parts:

211 Drugs-Manufacturing, Labeling, Laboratories, Packaging Containers

314 Administrative Practice and Procedure, Drugs

700 Cosmetics, Definitions, Prohibited Cosmetic Ingredients

Under Part 211, the regulation establishes a requirement for tamper-resistant packaging for O-T-C drug products which will improve packaging security and assure the safety and effectiveness of the drug products.[8] The regulation requires that O-T-C drugs for retail sale be in tamper-resistant packages. (See Appendix A for list of specific products affected.) These are defined as packages "having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred."[9]

Labeling for these products must contain a statement alerting consumers of the specific tamper-resistant feature of the package. This statement must be placed such that if the tamper-resistant feature were damaged or missing, the statement would be unaffected.[10]

The FDA does not specify what must be used to provide

tamper-resistance, but gives suggestions for currently available packaging systems which they believe are capable of meeting the requirement of their rule. Their intention is to leave the area open to new technologies, while specifying which currently available devices are considered appropriate.

Drug products that are not packaged in tamper-resistant packages, or are not properly labeled under 21 CFR 211, are considered to be adulterated or misbranded.[11]

These same general principles apply to new drug products and cosmetics under Parts 314 and 700 respectively.

The following indicates effective dates for 21 CFR 211.132:

I. Requirements for tamper-resistant packaging.

A. February 7, 1983.

1. For all O-T-C Drugs and Cosmetics most vulnerable to tampering.
   Includes: Oral, vaginal and rectal drugs (other than tablets and suppositories), otic drugs, nasal drugs, opthalmic drugs.

B. May 5, 1983.

1. For all tablets and suppositories which are less susceptible to tampering.
   Includes: Oral and vaginal tablets, and vaginal and rectal suppositories.

II. Requirement for label statement and requirement that barrier to entry be distinctive.

A. May 5, 1983.

III. Requirements that all stocks held for sale (including in retail stores) be in compliance with the regulation.

A. February 6, 1984.[12]

Some amendments have been made to the rule since its writing. Definitions have been clarified and products have been excluded from a part or all of the regulation. The FDA also stated that one of their previously approved tamper-resistant packages is no longer considered appropriate for this rule. The wet seal or cellulose band, as currently manufactured, does not meet the requirements of the regulation.[13]

A COMPARISON OF THE CHILD-RESISTANT AND TAMPER-RESISTANT PACKAGING REGULATIONS

The regulations requiring tamper-resistant and child-resistant packaging are very similar. Both affect the O-T-C drug industry, therefore similar economic effects would be expected. Unfortunately, this type of study was not done following the child-resistant regulation, so we cannot estimate the economic effects of tamper-resistant packaging by comparing the two.

What can be done, however, is to compare how and why the regulations were written and see which areas were likely to produce the largest economic effects. This might be important if the FDA does extend the tamper-resistant regulation to other industries, although in 48 FR 16660 they indicate no plans for broadening the scope of the regulation.[14]

Child-Resistant Packaging

The need for child-resistant packaging was recognized because children were dying from accidental poisonings caused by ingesting hazardous household products. In the early 1960's, the United States government began making efforts to decrease the number of these deaths. Their efforts centered around informational programs and various forms of publicity intending to teach adults to keep toxic substances out of the reach of children. These programs proved to be ineffective,

so in September of 1970, the government decided to take another direction in solving the problem. The FDA created a committee which proposed a set of performance standards for safety closures to be used on hazardous substances kept in the home. (See Appendix A for list of products covered.)

These standards were set in the Poison Prevention Packaging Act.[15] The special packaging required by the Act is intended to reduce the risk to small children by either preventing access to the substance, or by preventing access to a harmful amount of the substance. The regulation does not specify a specific type of package to use, but gives quantities and measurements which the designers must insure the package meets. The closures are to be tested and cannot be designated child-resistant unless they pass these protocol tests given in the regulation.

Tamper-Resistant Packaging

The reason for writing the tamper-resistant packaging regulation was different from the reason for child-resistant packaging. It was not accidental entry into the package that created the need for this regulation, but deliberate entry by someone intending to do harm, even before the product reached the home. Because many of these serious tampering crimes occurred in a short period of time, the FDA issued an immediate final rule. The lengthy preparation time available with the child-resistant regulation was not allowed for the tamper-resistant regulation.

The tamper-resistant packaging regulation does not

include an effectiveness test for the new packages as the child-resistant regulation did. There is no quantitative measure of exactly how resistant to tampering the package must be. This may prove to be a problem for the industry since the determination of whether a package shows "visible evidence" of tampering is a personal judgement. Some comments from a consumer focus group on tamper-resistant packaging reflect this variety of opinion. After being shown a bottle with a seal over its mouth, consumers said:

> "I'd feel better if there was an exterior device as well as (an) inner seal...something like a shrink band. Maybe it's silly, but I'd just feel more comfortable."[16]
>
> vs.
>
> "If you have a sealed bottle, then overwrap is superfluous packaging, even under the circumstances. I mean, I would feel comfortable enough with a film-wrapped package..."[17]

These differing opinions may result in economic effects for the pharmaceutical companies if consumers believe one type of tamper-resistant package is less effective than another.

PRE-REGULATION ECONOMIC PREDICTIONS FOR TAMPER-RESISTANT PACKAGING

The economic effects of this new regulation were a major concern to many during the preparation of its details. The government studied the parts of the industry that would be affected and made their predictions as to the extent of the impact. O-T-C industry members also made their own predictions, which tended to be quite a bit higher than those made by the FDA. These estimates will be summarized in the following section, and later compared with the actual results.

The economic consequences of the legislation were considered by the FDA before issuing the regulation. The expected problems were discussed in the Federal Register and the FDA's solutions were explained.

They felt that one single, early effective date for the regulation would cause unnecessary economic problems because the industry would be forced to compete for scarce resources. Those companies unable to get the resources would have to discontinue marketing their product after the effective date. This would also produce a "serious strain" on the packaging machinery industry, which might not be able to produce the needed equipment. These problems would make the cost of compliance unnecessarily high for the manufacturers and, in turn, the price of O-T-C drugs to consumers.

As a solution to these potential problems, the FDA issued sequential effective dates. This spread the demand for the resources over a longer period of time, allowing supplies to meet demand and insuring that the highest risk products would be tamper-resistant immediately.

In order to eliminate the costs associated with immediate removal of non-complying products from the retail shelves, the regulation would have to apply only to those products produced after a final effective date. The seriousness of the problem, however, suggested that a final effective date be set, after which all products sold would have to be in tamper-resistant packaging. The earlier this date was, the higher the costs associated with that step would be.

To reduce these problems, the FDA set their final date 15 months following the regulation's writing and explained why they expected this to create few problems. The FDA believes "the market will be significantly depleted of products in non-tamper-resistant packaging within a relatively short period of time," therefore the retail level effective date of February 6, 1984, will have little economic effect.[18] Even after this statement, the agency indicated that they were uncertain of future economic problems, therefore they are allowing for changes in this area. Potential economic effects will be observed and if they are found to be severe, the agency will review the need for the date and what that date should be. This will happen far enough before the retail level effective date occurs, that any changes can be taken into account by those who will be required to use it.

These economic problems were considered by the FDA before the issuing of the regulation, hoping they could reduce or prevent high costs to the industry. There were many other economic effects which could not be avoided, and the FDA tried to estimate these costs. The following list summarizes the FDA's expected economic effects caused by this regulation.

The FDA did put dollar values on their estimates. The following quotes and estimates come from 47 FR 50449:

> "The rule will affect approximately 2 billion retail packages per year."
>
> "Approximately 10-30 percent are already packaged in ways defined as tamper-resistant, therefore will only need labeling statements and distinctive indicators or barriers to entry."
>
> "All costs seen are not all attributable to final rule since it can be expected that many manufacturers would have gone to some sort of tamper-resistant packaging even without the regulation."
>
> "Expert Technical Committee on Tamper-Resistant Packaging estimated unit costs of tamper-resistant packaging to range from a fraction of a cent for some popular packaging systems, such as shrink seals, to several cents per unit for bubble packs and manual seals."
>
> "If unit costs average 1.0 to 2.0 cents per retail package, aggregate recurring costs for tamper-resistant packaging would be $20 - $40 million per year."
>
> "Costs for new packaging equipment is not expected to have a significant impact on the average cost per package. The cost of packaging equipment varies widely from less than $100 to over $100,000 per unit."
>
> "The one time change in labeling for all affected products is expected to cost $5 - $10 million."
>
> "The agency does not believe that the industry will experience significant costs for stocks of obsolete packaging at the six month effective date."

> "The 15 month retail level effective date may result in some returns of non-tamper-resistant packages to manufacturers." The agency believes these will be "very small" in volume and confined to the smallest retail level.
>
> "Thus, the agency believes that the total cost of conversion to tamper-resistant packaging would not be sufficient even in its entirety to warrant designation of the rule as a major rule."

Other economic predictions were made after the regulation was written. The Proprietary Association estimated that new packaging for the non-prescription drug industry would cost the consumer 2 cents to 10 cents per package.[19] An analyst with a leading securities firm predicted that better closures would raise prices 1 percent to 2 percent.[20] Another potential economic problem area is the area of product liability. Non-compliance with the regulation can cost anywhere from $2000 to $50,000, but compliance does not guarantee protection from these fines.[21] In the case of deliberate product tampering which results in injury, juries will decide the extent of compliance and whether the manufacturer is free from liability. Insurance for the manufacturing companies may protect them from huge liability suits, but will also add to the cost of O-T-C products.[22]

Economic predictions were also made for the supplier industry affected by this regulation. Many felt the suppliers would benefit by increased sales volume. Some supplier companies observed a sudden increase in stock value immediately following the regulation, an obvious indication that experts expected a significant increase in business for the tamper-resistant packaging suppliers.[23]

ECONOMIC STUDY

Reasons for Study

This study was done in order to investigate the economic effects of the new tamper-resistant packaging regulation on all companies involved. The information might be important to members of the industry who are interested in estimates of implementation costs for tamper-resistant packaging. The information could also be helpful to the FDA, to determine problem areas of this regulation. This would be useful if the government extends the regulation to the food or cosmetic industry, although the FDA currently maintains that the scope of the rule will not be broadened.

Methodology

The findings of this study are based on information derived from questionnaires sent to 138 companies who are in some way involved with tamper-resistant packaging. Some of these were drug manufacturing companies which were required to use tamper-resistant packaging for some of their products and others are those companies which supply the materials, components and equipment used to make tamper-resistant packages. A variety of these companies were contacted (82 suppliers and 56 users) and asked to specify exactly how this regulation affected them economically. Not only were specific topics

covered, but comments were encouraged to explain misleading dollar values or other irregularities. Those who received the surveys were also asked to indicate any economic effects their company may have seen which had been overlooked in the survey. Although these commments resulted in information not given by all respondents, they also allowed for clarification of answers which might otherwise have been misunderstood.

Before the actual study was done, a test survey was used to improve the quality of the questions and to insure that no economic areas were omitted. Sample surveys were sent to two material suppliers, two machinery suppliers and two pharmaceutical companies.

After revisions were made, the actual surveys were sent out with a cover letter explaining the study, a stamped-return envelope, and a phone number to call if any questions arose. The respondents were given one month to complete the survey. (See appendices H & I for surveys.)

Sampling Process

Population:

It is difficult to determine the population sizes for the tamper-resistant packaging industry. It is only a small portion of a much larger industry and it is often hard to separate the two.

The 1983 Physicians Desk Reference for Non-Prescription Drugs was used to determine the population size for the drug manufacturing companies. From this reference, all the

companies which manufacture O-T-C drug products covered by the new regulation were counted. The total number of these companies came to 82.[24] This number was verified by a member of the Proprietary Association who said their association consists of approximately 80 members who represent 80-90% of the industry.

Determining the population size of the tamper-resistant packaging supplier industry was not as direct. The 1983 Packaging Encyclopedia Buyers Guide for Packaging Materials was used to find all United States suppliers of packaging materials, components or machinery which could be used to produce tamper-resistant packages. The categories used for the count were:

A. In the Machinery Section:

1. Blister form, fill and seal
2. Tamper-proof capping
3. Neckband applying
4. Tamper-indicating labeling
5. Shrink packaging, sleeve wrapping
6. Shrink tunnels

B. In the Packaging Supplies and Materials Sections:

1. Tamper-indicating closures
2. Cellulose bands
3. Foil bands
4. Plastic bands
5. Blisters (for this study blisters and bubbles are being considered the same for two reasons; The Glossary of Packaging Terms gives almost identical definitions for the two package forms and people in industry seem to interchange the two terms.)

This estimate of population size may be much larger than is actually true because I cannot be sure that all companies on this list supply materials to the O-T-C drug industry. I have excluded all distributors of these packaging materials from the list because they only sell the materials produced by those companies already counted. Using this method, the population size for tamper-resistant packaging suppliers was determined to be 332, but it is likely that the actual number is much smaller.

Sample Size and Content:

The sample used for the O-T-C drug manufacturing industry consists of 56 companies from throughout the United States (68.3% of the population). Because survey responses tend to be better when sent to a specific individual rather than a general title, these surveys were sent to employees who have had some contact with Michigan State University. The names came from lists of people attending industry courses at the Michigan State University School of Packaging, interviewers at Michigan State University's Placement Center, Michigan State University alumni and others known by members of the Michigan State University School of Packaging.

The supplier company sample consists of 82 suppliers (24.7% of the population) from all over the United States. These names also came from a variety of different lists, including placement service interviewers, former Michigan State Univeristy Packaging students, advertisers in various

packaging magazines, tamper-resistant packaging suppliers from a Packaging Digest list, members of the PMMI packaging show in November 1982, and contacts of the Michigan State University School of Packaging.

Although the samples came from lists, the author believes the purpose of the lists were diverse enough to prevent the problem of too much similarity between companies sampled.

Sampling Method:

The sampling method used is similar to a disproportional, unequal, stratified sampling plan (or controlled sampling).[25] In this type of sampling plan, unequal numbers of the different categories (stratums) are used and the actual numbers used are not proportional to the total population. Unequal sample sizes are appropriate in this study because we are not trying to compare the two samples (drug manufacturers and suppliers). The samples are disproportional because it would have been uneconomical and impractical to make them both proportional to their population size. Sampling the same percentage of suppliers and users would have required a supplier sample size of well over 100 companies, something I was unable to do. Reducing the number of drug companies sampled in order to get their percentage as low as that of the suppliers would have resulted in a sample size of twenty - a number too low for statistical accuracy.

Time of Study:

The study was conducted during May of 1983, soon enough after the regulation's writing that the information was still uncollected, but late enough that most companies had time to gather the costs.

GENERAL RESULTS OF PHARMACEUTICAL COMPANY SURVEYS

Pharmaceutical survey data is contained in Appendix J.

Of the 56 surveys sent to the drug manufacturing companies, 20 were returned as usable. The 20 surveys were used to calculate a return of 35.7%, a typical return percentage according to our survey specialist.

Five out of the 20 surveys returned were considered not applicable because they did not supply the over-the-counter market. One other questionnaire said it was too early for them to give exact dollar figures and they felt estimates were not appropriate for our study. After substracting these surveys which were not applicable to our study, a total of 14 usable questionnaires were obtained. This represents a usable return of 25%, which is 17% of the total industry.

TABLE 1

SIZE OF POPULATION, SAMPLE AND RETURNS FOR PHARMACEUTICAL COMPANIES

	Population	Sample	Returned Surveys	Usable Surveys
Number	82	56	20	14
% of Sample			35.7%	25.0%
% of Population		68.3%	24.4%	17.1%

Area of Responsibility

Question 1 asks for the area of responsibility of the person completing the questionnaire. The purpose of this was to see if a certain type of employee was more likely to complete the survey. Almost all of the returned forms were completed by a member of some sort of packaging department. This is probably because the packaging people are most directly affected by this regulation, the most knowledgeable about the subject and therefore, more likely to complete the questionnaire.

TABLE 2

RESPONDENT'S AREA OF RESPONSIBILITY
PHARMACEUTICAL COMPANIES

Packaging	12
Production/Manufacturing	1
Purchasing	1
TOTAL	14

Company Description

Questions 2 and 3 give descriptions of the companies questioned: the general purpose of the firm and whether its market is local, regional, national or international. These questions were intended to insure we did not have responses from people not affected by the regulation. The results show that one national and thirteen international pharmaceutical companies responded to our survey. This is fairly typical of most of the United States pharmaceutical companies, many of which are subsidiaries of large international corporations.

Annual Sales

This question asked for the annual sales of the responding companies. We wanted the sales for the divisions involved in tamper-resistant packaging so that we might find what portion of the business tamper-resistance occupies. This was not possible, however, since it appears that everyone responded with total corporation sales. Another reason for asking this question was to determine the difference in size of those companies surveyed. The companies participating in the study range in size from $100 million in annual sales to over $1 billion (see Table 3 for number of responses from each sales dollar range). Most United States pharmaceutical companies are very large (sales over $100 million), but there are a few smaller companies. These small firms did not respond to our survey, therefore their economic effects are unknown and not necessarily the same as for the larger companies.

TABLE 3

SALES VOLUME
(PHARMACEUTICAL COMPANIES)

Sales Volume	Number of Responses
$ 5 - $ 10 Million	
$ 10 - $ 50 Million	
$ 50 - $100 Million	
$100 - $250 Million	2
$250 - $500 Million	4
$500 - $750 Million	
$750 - $ 1 Billion	1
$1 Billion and Over	5
No Answer	1
Unknown by Respondent	1
	14

Products Affected by Regulation

Question number 5 asks how many different products each company manufacturers which are affected by the tamper-resistant packaging regulation. This shows another aspect of company size; some responding companies have as few as two O-T-C products which are affected by the new regulation while others have as many as 29 (see Table 4 for various measures of company size). Some comments indicate that at least one company feels they have too many products affected by the regulation to even list them all. The number of products affected by the regulation at each company varies widely, but the average number is 6.58 products per company.

TABLE 4

DIFFERENT MEASURES OF COMPANY SIZE

Survey Number	Annual Sales	Number of Products Affected by Tamper-Resistant Legislation	Annual Production of Products Affected by Tamper-Resistant Legislation*
1	$250 - 500 Million	2	1,500,000 packages
2	$250 - 500 Million	4	
3	Unknown	2	
4	$1 Billion and Up	7	
5	$150 - 250 Million	6	60,000,000 packages
6	----------	All	
7	$1 Billion and Up	3	250,000 packages
8	$1 Billion and Up	5	
9	$750 Million - $1 Billion	29	
10	$250 - 500 Million	6	
11	$100 - 250 Million	4	3,500,000 packages
12	$250 - 500 Million	5	30,000,000 packages
13	$1 Billion	All	
14	$100 - 250 Million	6	
Averages		6.58	19,050,000 packages

*Taken from Question 9 - I am assuming that labor costs are being amortized over yearly production of tamper-resistant packages.

Number of Products Tamper-Resistant Before the Regulation

The companies were asked how many of their products which must be made tamper-resistant were already in tamper-resistant packages before the regulation (see Table 5 for tamper-resistant packages used before the regulation). The responses varied with some companies having all of their products in tamper-resistant packages and others having none. The average company had 34.7% of their products which were affected by the regulation in packages currently accepted as tamper-resistant. Most did indicate that the graphics on these packages would still have to be changed.

The second part of Question 6 deals with the products that require package changes. The companies were asked to indicate which of their products were getting new packages, what tamper-resistant materials were being used and the cost of these materials. It has been determined that shrink seals and bands are the most popular tamper-resistant material being used, but it is impossible to say exactly how many products are using each material. Because of this, a straight average was calculated for material cost where using a weighted average would have been more appropriate and would have resulted in a higher average material cost per package. Using this method, the average tamper-resistant material cost for the pharmaceutical companies is 1.4 cents per package. This material cost is approximately equal to the FDA's estimated total cost increase per package.

TABLE 5

MOST COMMON TAMPER-RESISTANT MATERIALS
IN USE BEFORE THE REGULATION

Tamper-Resistant Device	Number of Responses Indicating Use
Strip/blister packs	8
Bottle seals (many types)	6
Neck bands	1
Foil Pouches	1

TABLE 6

PERCENT OF PACKAGES ALREADY TAMPER-RESISTANT BEFORE THE REGULATION

Survey Number	Number of Products Affected by Tamper-Resistant Legislation	Number of Products Not Requiring a Package Change Because of Regulation	Percent Currently Tamper-Resistant
1	2	0	0
2	4	1	25%
3	2	2	100%
4	7	0	0
5	6	0	0
6	All Products	0	0
7	3	0	0
8	5	5	100%
9	29	0	0
10	6	0	0
11	4	3	75%
12	5	2	40%
13	All O-T-C Products	1	0
14	6	2	33%
Total	79	16	
Average	6.58	2.29	34.74%

TABLE 7

MOST COMMONLY USED TAMPER-RESISTANT MATERIALS AND DEVICES
AND THE AVERAGE COST PER PACKAGE

Material/Device	Ranking of Most(a) Often Used Material By Estimate of Number of Products Using Each Device	Number of Companies Using Device	Average Cost(b) Per Package
1. Film Wrappers	4	2	$ .03
2. Blister or Strip Pack	4	2	-
3. Bubble Pack		0	
4. Shrink Seals or Bands	1	10	$ .0244
5. Sealed Cartons	2	4	$ .0056
6. Adhesive		0	
7. Foil, Paper or Plastic Pouches	4	2	-
8. Bottle Seals	2	4	$ .0122
9. Tape Seals	4	2	$ .01
10. Breakable Seals	5	1	$ .007
11. Sealed Tubes	3	3	$ .01
12. Aerosol Containers		0	
13. Other (graphics only)		2	$ .0001
AVERAGE			$0.0144067(c)

(a) Actual number of different products using each device is very hard to determine due to form of responses.

(b) The actual costs of each device varied quite a bit, even between different products within the same company.

(c) Average determined by number of companies using each (because actual number of products using each device cannot be determined).

Machinery Purchases

Question seven was used to determine whether the pharmaceutical companies had to purchase additional machinery or equipment to help them produce tamper-resistant packages. Most companies had to purchase some type of equipment which added to their costs from this regulation. The average company purchased four machines at a total cost of $150,655. The maximum number of pieces of equipment purchased was 14 and the maximum total price paid by a company was $820,000. Although the initial outlay for these machines could be very high, when depreciated and amortized over the number of packages they produce, cost per package is very small.

The four companies that did respond to this question with per package costs show that the average cost increase due to machinery purchases is 1.85 cents per package. The FDA had originally predicted that machinery costs would be insignificant, but because the average cost is almost 2 cents per package, they would probably feel differently now.

Line Speeds

The purpose of Question 8 was to see if the pharmaceutical companies had decreases in their line speeds because of the regulation. Costs for this cannot be determined because of the different factors which can cause slower speeds: use of manual labor, generally slower equipment or more downtime. Each factor has a different costs associated with it and those will have to be determined by each individual company. It may

be easier to assign a cost estimate to this problem knowing that the average company experienced a 19% decrease in line speed because of the need for tamper-resistant packaging. The range of reductions in speed went from 5% to 50%, so some companies are running at one-half their original speed which can be very costly. Comments from our repondents indicate that not all of these slower speeds are permanent. Some required temporary manual labor during the change-over process and one company indicated that only some of their new packages (5%) required line speed reduction.

Labor Changes

This asks if the pharmaceutical companies experienced a change in labor costs due to the tamper-resistant regulation. It is related to Question 9 in that the slower line speeds may be a result of an increase in the use of manual labor. Fifty percent of the group did mention that the regulation resulted in an increase in the number of man hours required to maintain production. Costs, again, will vary with each company, depending on their wage rates and the number of increased hours. Cost increases for the sample group ranged from $16,000 to $200,000 and were to be amortized over 250,000 to 60 million packages. This makes the average cost increase due to labor less than a penny per package (0.39 cents). Some of these labor changes were only temporary and could have gone as high as 50% for certain companies.

Although the norm appears to be an increase in labor usage, one company did say they experienced a $60,000

decrease in labor hours, to be amortized over 3.5 million packages (1.7 cents per package).

Graphics Changes

Question 10 asks whether the pharmaceutical companies had additional costs due to graphics changes required by the regulation and all companies questioned said yes.

Some companies responded with costs per package of $0.0003 to $0.00225 for various packages. A few comments incated that cost per package would be "minimal" or "insignificant." Others gave total costs ranging from $100 per package type to $500. These costs were generally one time, mecanical changes or plate changes. Another graphics cost that one company felt would be significant was the scrap resulting from the May 1983 deadline, but they did not estimate the dollar value of this.

Total cost per company depends on how many products required the new graphics. For this study, total costs ranged from $200 to $1500. These costs will be insignificant for the high volume pharmaceutical industry.

Reasons For Choosing Tamper-Resistant Devices

Question 11 tells why the pharmaceutical companies chose the particular tamper-resistant devices that they did. Cost was not mentioned as a major factor in itself; effectiveness and compatability with existing packaging had more bearing on their decisions. Some companies also said more than one factor was considered in making their decision. Two companies

claimed to have chosen the "most effective option," but not surprisingly, they are using different devices.

Although this question did not pinpoint one major reason for choosing the tamper-resistant device used, it did show that cost seems to be an important factor, and system compatability was the method used to keep costs down.

Advertising Changes

Question 12 asked the pharmaceutical companies if they made any advertising changes because of the new packaging. All companies responded with a "no" except one that felt this question did not apply. It is obvious, however, that many of these firms are currently advertising the fact that they now have tamper-resistant packages. The contradictions between their responses and their actions may mean that they did not increase the amount of advertising being done, but only the content of their current ads.

Costs Due to Retail Effective Date

The regulation has a final retail level effective date after which all packages on the retail shelves must be in complying packages. Because it is possible for the companies to experience losses due to this requirement, I asked what they planned to do with these non-complying packages, and what losses they expected. One company felt this either did not apply to them or the costs were unavailable, while the other 13 said they expected most non-complying packages to be gone by that time. One of these companies obviously expected to

have some packages left on the shelves (200,000), which they will repackage, at a cost for materials and labor, of $11,600. They also said they expected a loss of approximately $15,000 because of packages returned to them after that date.

Sales Volume Changes

This question asked whether the pharmaceutical companies expected any change in sales volume because of this regulation. It was expected that some companies might increase their market size if they became tamper-resistant much faster than the competition, if they were always tamper-resistant, or if they had a better tamper-resistant solution than the competition. Only one company indicated an expected volume increase of 1.3 million packages, but they did not comment on the reason for this.

Effect on Cost to the Consumer

The final question asks whether the companies expected their cost increases to be passed on to the consumer and if so, what the cost per package would be. One half of the responding companies said they are not going to pass the costs on to their customers, but only one estimated they would be absorbing 2 - 3 cents per package. Those passing their costs on are expecting to increase prices up to 15 cents per package (average is 7.5 cents), well over the FDA prediction of 1 - 2 cents.

GENERAL RESULTS OF SUPPLIER SURVEY

Supplier survey data is contained in Appendix K.

Of the 82 surveys sent to the various supplier companies, 48 were returned. This means that 59% of the sample completed the questionnaire, a return percentage better than expected for this type of survey. Eight of the 48 surveys returned were not applicable either because they did not supply the O-T-C trade, they did not know who used their materials or they were distributors of supplies only. Excluding these 8 surveys, there were 40 usable questionnaires. This means 49% of the sample responded with usable data and 12% of the total industry contributed to this study.

TABLE 8

SIZE OF POPULATION, SAMPLE AND RETURNS FOR TAMPER-RESISTANT SUPPLIER COMPANIES

	Population	Sample	Returned Surveys	Usable Surveys
Number	332	82	48	40
% of Sample			58.5%	48.8%
% of Population		24.7%	14.5%	12.1%

The first four questions of this survey relate to basic information about the company and the employee who completed the survey.

Respondent's Area of Responsibility

This question asks the person responding to explain their specific area of responsibility. The surveys were filled out by people from many different areas within the company, but most came from members of the sales or marketing departments (24). These again, are the departments most knowledgeable about tamper-resistant packaging for this type of of company.

TABLE 9

RESPONDENT'S AREA OF RESPONSIBILITY (SUPPLIERS)

	Marketing/ Sales	Corporate Management	Packaging	Production/ Manufacturing	Regulatory Affairs	Other
Machine Suppliers	7	1	1	1		1 owner
Components Suppliers	13	8	1	1	1	
Suppliers of Both Machines and Components	4		1			
TOTAL	24	9	3	2	1	1

Company Description

This question asks for the general purpose of the responding companies in order to get a description of the company and the different tamper-resistant materials they supply. It turns out that the supplier companies can be separated into three different groups: those that supply machinery used to make or apply tamper-resistant devices, suppliers of tamper-resistant or tamper-evident materials, closures, or containers, and those who supply both machinery and materials.

This division will be used throughout the rest of this paper so that economic comparisons can be made between similar supplier companies. Most of these companies had international sales, but we had respresentatives with national, regional and even local sales areas.

TABLE 10

NATURE OF BUSINESS - SUPPLIER COMPANIES

	Machinery	Materials	Closures	Containers	Machinery and Closure	Machinery and Material
Machine Suppliers	11					
Component Suppliers		10	12	2		
Suppliers of Both Machines and Components					3	2
TOTAL	11	10	12	2	3	2

Annual Sales

Question 4 asks for the annual sales of the supplier companies. In order to determine whether the economic effects of the tamper-resistant packaging regulation were different for small and large companies, the companies had to be separated by size. The measurement of size used was sales volume per year, which ranged from zero to $250 million annually. There were some differences between sales of the three different types of suppliers; the companies supplying both materials and machinery tended toward the higher end of the scale, while the machinery only suppliers were never quite that high (see Table 11).

TABLE 11

SALES VOLUME - SUPPLIER COMPANIES

	Unanswered	$5 Million And Under	$5-10 Million	$10-50 Million	$50-100 Million	$100-250 Million
Machine Suppliers	4	1	5	1		
Component Suppliers	3	11		7	2	1
Suppliers of Both Machinery and Components				2	1	2
TOTAL	7	16	5	10	3	3

NOTE: No company had a sales volume over 250 million dollars.

Products Supplied by Surveyed Companies

These questions tell which materials and equipment are supplied by the companies questioned. The results show that the responding questionnaires came from companies supplying all FDA recommended tamper-resistant devices except aerosol containers. They supply fifteen different types of materials and a large variety of equipment used to produce or apply these materials (see Appendix K, Questions 5 and 6, for a list of specific materials and equipment supplied).

New Equipment Purchases

This question asks whether the supplier companies increased production capacity and, if so, did they do so by buying new equipment. Many of these companies did need to increase their production capacity because of the new tamper-resistant packaging regulation and some of them will do this by purchasing new equipment. The companies needing new equipment were the material and component suppliers who had to purchase many different types of equipment, therefore spent different amounts of money (see Table 12 for average machinery costs and see Appendix K, Question 7, for exact pieces purchased).

The maximum amount spent was close to $3 million for one company, but the majority of the companies reported no costs for new equipment. Because of this, the average costs do not have much meaning. Machinery costs for supplier companies intending to see an increase in demand depends on whether they

currently have excess capacity of whether they are expanding their product line because of this regulation.

TABLE 12

AVERAGE MACHINERY/EQUIPMENT COSTS
TO SUPPLIER COMPANIES

	Average Number Machines Purchased	Average Cost Each Machine	Total Cost (Average)
Machine Suppliers	0	-	-
Component Suppliers	7.6	$100,160	$758,357
Suppliers of Both Machines and Components	0	-	-
TOTAL	7.6	$100,160	$758,357

Labor Changes

This question asks about labor changes caused by the regulation. Although it was determined that most supplier companies experienced no change in the quantity of laborers used, 28% of them increased their production capacity by increasing labor hours. The actual number of hours associated with this increase in labor can only be surmised. Only one company responded to that portion of the question, and even then, they indicated an increase of 750 hours but did not say what unit of time that covered. One company did give a dollar value of $25,000 to their additional labor costs and another said it was difficult to measure (see Table 13).

TABLE 13

LABOR CHANGES FOR SUPPLIER COMPANIES DUE TO TAMPER-RESISTANT LEGISLATION

	No Answer	No Change	Increase	Decrease	Average Increased Cost
Machine Suppliers	1	8	2		$25,000*
Component Suppliers	1	14	9		0
Suppliers of Both Machines and Components		5			0
TOTAL	2	27	11	0	$25,000

*Determined from one response only.

Advertising Changes

Question 9 asked about the changes in advertising caused by the tamper-resistant regulation. Approximately 40% of the suppliers questioned chose to increase their advertising expenditures by either 50% or an average of $21,916 per year (see Table 14). The machinery companies appear to be making the largest changes in advertising dollars, while the other types of suppliers are spending a little less.

TABLE 14

CHANGES IN ADVERTISING COSTS FOR SUPPLIER COMPANIES
FOR ONE YEAR FOLLOWING THE TAMPER-RESISTANT LEGISLATION

	No Response	No Change	Decrease	Increase	Average Dollar Increase
Machinery Companies	1	6		4	$27,500
Material/Device Suppliers		12	1	11	$22,166
Suppliers of Both Machinery & Materials		2		3	$17,500
TOTAL	1	20	1	18	$21,916*

*Two companies gave no dollar figure, but indicated that they experienced a 50% increase in advertising costs.

Sales Volume Changes

Question 10 asks whether the supplier companies experienced any variation in sales volume due to the tamper-resistant packaging regulation. Many people expected the regulation to cause an increase in sales for anyone supplying materials, components or machinery to the pharmaceutical companies. For over 60% of the supplier companies, these expected increase occurred. This was especially noticeable for the materials/device suppliers who expected average sales volume increases of $2,835,625 this year. One of those companies who indicated a dollar increase of $4 to $5 million said this was an increase of 100% for them. The average increase for all types of suppliers was $2,177,916 per year (see Table 15 for average costs). Although 62% of the suppliers expect to experience sales increases, only one-half of those actually gave dollar estimates, therefore, these averages have been determined from twelve responses.

TABLE 15

CHANGES IN SALES VOLUME FOR SUPPLIER COMPANIES FOR ONE YEAR FOLLOWING THE TAMPER-RESISTANT LEGISLATION

	No Response	No Change	Decrease	Increase	Average Dollar Increase
Machine Suppliers	1	2		8	$1,066,666
Component Suppliers		8		16	$2,835,625*
Suppliers of Both Machines and Components		4		1	$ 250,000
TOTAL	1	14	0	25	$2,177,916

*One respondent said his company expected sales to increase by 100%.

Effect on Cost to Customers

With Question 11, we tried to see whether the supplier companies were going to increase the cost of their product to their consumers (pharmaceutical companies). There were some obvious problems in understanding the intended meaning of this question. The question and responses read as follows:

> Do you expect your additional costs caused by this regulation to be passed on to your customers?
>
> - We did not incur additional costs due to this regulation.
> - Yes, we will pass costs to our customers.
> - No, we will absorb additional costs.

Many people, after having written that they purchased new machinery, increased their labor hours and/or have almost doubled their advertising costs, responded to the above question by saying "we did not incur additional costs due to this regulation."

Some possible reasons for this discrepancy might be that their increased sales volume has offset any other costs or, as one company mentioned, they have identified new products due to this regulation, therefore the costs are being applied to new product development. A machine supplier qualified his response by saying that "cost per machine did not increase because of increased production."

It is possible that these companies did not actually see any additional costs caused by the tamper-resistant legislation. If we assume that everyone did understand the question accurately, 62.5% of the supplier companies did not incur any

cost increases, and 27.5% did, and will pass the cost to their customers.

Another problem occurred with this question; a few companies indicated no cost increases from the regulation, but said they will pass the costs on to their customers. Does this mean they are going to take advantage of the situation and increase their prices? (See Table 16)

TABLE 16

WILL SUPPLIER COMPANIES PASS INCREASED COSTS ON TO THEIR CUSTOMERS?

	No Response	Did Not Incur Additional Costs	Yes	No
Machine Suppliers	1	9	1	
Material/Device Suppliers	3	12	9	
Suppliers of Both Machines and Components	0	4	1	
TOTAL	4	25	11	0

PRODUCT PRICE CHECKS

As a secondary study to check the responses received from the survey, three Lansing area wholesalers we asked to give cost information on products affected by the tamper-resistant packaging regulation. The current selling price of selected O-T-C products were checked and compared to their prices before the regulation. Although we are not suggesting that all manufacturers have raised their prices since this regulation, we do know that all of the products checked (12) did increase in price. The wholesale prices rose between 13 cents and 57 cents per package in the past few months, increases of seven to 36 percent. Comments from retailers indicate that they have noticed a general trend toward more expensive products, especially those with the most obvious package changes.

Another method of checking retail price changes was to purchase three different O-T-C drug products at area drug-stores and supermarkets. This was done immediately following publication of the rule; after each effective date of the regulation, the same products were purchased at the same stores and these prices were compared to the originals (Tables 17 and 18). These particular products showed price increases of 4.9% to 28.8% between December 1982 and July

TABLE 17

SUPERMARKET PURCHASES

Product	PRICE 12/18/82	PRICE 3/18/83	PRICE 6/18/83	Total Percent Increase
Aspirin (a) 50 tablets	$1.22	$1.22 with tamper-resistant message	$1.28 with tamper-resistant message	4.9%
Acetaminophen 50 tablets	$1.93	Not Available	$2.07 with tamper-resistant message	7.2%
Cold Capsules (b) 10 capsules	$1.97	$1.97 with tamper-resistant message	Not Available	0

(a) Product came in sealed carton, therefore was always considered tamper-resistant.

(b) Product came in blister package, therefore was always considered tamper-resistant.

TABLE 18

DRUGSTORE PURCHASES

Product	Price 12/3/82	Price 2/28/83	Price 5/22/83	Price 7/20/83	Total Percent Increase
Aspirin (a) 50 tablets	$1.29	$1.29 with tamper-resistant message	$1.39 with tamper-resistant message	$1.39 with tamper-resistant message	7.8%
Acetaminophen 24 tablets	$1.39	$1.69	$1.79 with tamper-resistant message	$1.79 with tamper-resistant message	28.8%
Cold Capsules (b) 10 capsules	$1.99	$1.99	$1.99	$2.29	15.0%

(a) Product came in sealed carton, therefore was always considered tamper-resistant.

(b) Product came in blister package, therefore was always considered tamper-resistant.

1983. Two of these products were already available in packages considered tamper-resistant, and their prices still rose.

The largest price increase found was 40 cents a package for a 24-tablet acetaminophen product, much higher than the FDA prediction of 1-2 cents. It is probable that these price increases are not solely a result of the need for tamper-resistant packaging, but also include other factors such as inflation. It might be assumed, however, that because the companies are raising prices so much beyond their actual costs, that they are anticipating future costs.

What is interesting about these results is the fact that every product checked had a substantial price increase, but only 50% of the companies surveyed indicated they would be passing the costs on to the consumer.

ERRORS

It is possible that any or all of the items from the following list may have occurred, and might have, in some way, biased these results.

1. The sample was not an actual random sample, therefore may not properly reflect the entire industry.

2. The survey questions may have been misunderstood, therefore the given answers may not reflect what was actually being asked.

3. With this type of survey, the respondents may have felt compelled to inflate their costs a little in order to justify their price increases.

4. Not all questions were answered by all respondents, therefore many average costs were determined using only a few responses, and should be interpreted accordingly.

CONCLUSIONS

RESULTS

The results of this study can be separated into two categories: costs to pharmaceutical companies and costs to supplier companies.

As expected, the pharmaceutical companies experienced substantial economic effects due to the new tamper-resistant packaging regulation. The areas which caused increased costs for these companies are: materials used in making tamper-resistant packages, equipment used to produce or apply tamper-resistant packages, graphics changes required by law and labor increases required to meet FDA deadlines. Some companies will also experience costs from lost product after the retail level effective date. The average total cost for each pharmaceutical company is $703,795. This includes all previously mentioned costs, even material costs (material costs averaged 1.4 cents per package; the total cost will depend on yearly production which varies widely between these companies). The average cost increase per package is 3.7 cents which includes material, new equipment, graphics and labor costs (see Table 19). Costs associated with decreased line speeds and costs associated with lost product after the retail effective date are not included in this per package figure. The decreased line speed average of 19% will probably result in significant

TABLE 19

AVERAGE COSTS - PHARMACEUTICAL COMPANIES
WITH ANNUAL PRODUCTION OF 19,050,000 UNITS (a)

	AVERAGE COST PER PACKAGE	TOTAL COST FOR EACH COMPANY FOR 1ST YEAR FOLLOWING TAMPER-RESISTANT LEGISLATION
Tamper-Resistant Materials	1.4 cents (b)	$266,700
New Equipment	1.9 cents (c)	$361,950
Graphics Changes Required by Regulation	0.005 cents	$ 850
Labor Costs Caused by Tamper-Resistant Regulation	0.39 cents	$ 74,295
TOTAL	3.8 cents*	$703,795*

(a) 19,050,000 is the average production per year for the pharmaceutical companies that responded to this study.

(b) Actual number of products using each material was not possible to determine. We noticed, however, that the most commonly used materials are also the most expensive, therefore, if a weighted average could have been used, this figure would be higher.

(c) Not all companies responded to the cost per package portion of this question; some mentioned that this cost would be minimal.

*These total costs do not include costs associated with decreased line speeds and lost or repackaged product following the retail effective date. Because these costs seem to be significant, the pharmaceutical companies should note that the average company experienced a 19% decrease in line speeds. Average costs associated with the retail level effective date can not be calculated, but one company did note that they expected losses of $26,000.

production cost increases for all companies, therefore, the lack of this information should be noted when considering average per package costs. Even without including all factors in this total, it is clear that the pharmaceutical companies are paying almost double what the FDA predicted they would pay. The original FDA estimate is so close to the material costs actually experienced by these companies that it is possible that material costs were all that agency considered when proposing the regulation.

Although the pharmaceutical companies had increased costs averaging 3.7 cents per package, they report to be increasing the price of their product an average of 7.5 cents. Our own limited observations show that the average price increases at the retail level are closer to 16.7 cents per package. This means that consumers will be paying much more for O-T-C drugs than the regulation actually cost the industry.

The second portion of the study shows the economic effects seen by the tamper-resistant supplier companies. These companies experienced their highest costs due to their need for new equipment to meet the increased demand for their products. These companies increased the amount of labor used and the amount of advertising done. The total cost increase for the average supplier company was $805,273 per year. These costs were offset by their increases in sales volume however, so in effect, the suppliers were not adversely affected by the regulation. (See table 20 for average costs to supplier companies.) Some companies said they experienced no additional

TABLE 20

AVERAGE COSTS - SUPPLIER COMPANIES

	Average Number Of Units	Average Cost Per Company
New Equipment	7.6 pieces	$758,357
Labor Changes	750 hours (1)	$ 25,000
Advertising	(2)	$ 21,916
TOTAL COST		$805,273

(1) Based on one response only.

(2) Two companies indicated that they increased advertising costs by 50%.

Sales Volume Increase	= $2,177,916
- Total Costs	= $ 805,273
Actual Gain for Supplier Companies	$1,372,642

costs due to this regulation, but they did indicate they were increasing product costs to their customers.

In general, it seems that no matter what costs were incurred because of this regulation, both the supplier and pharmaceutical companies are increasing the price of their product more than their cost increases. One reason for this might be that these companies are trying to cover costs they expect to incur in the future. For the pharmaceutical companies, one of these potential costs might be the losses from returned product with typical manufacturing defects which the customer will not buy. These defects may be seen by the public as signs of tampering. It is also possible that there will be additional costs from this regulation which have not yet been discovered and costs which have been ignored by this study and its participants.

IMPLICATIONS

The packaging industry was not prepared for this sudden packaging legislation and its associated costs. This study is not intended to predict all future costs caused by packaging legislation, but should give a guide as to what areas might be of concern to most companies.

Below is an example of the total cost equation developed for this particular regulation. Each cost area was weighted in order to reflect its contribution to total cost. Material costs, which are generally fairly simple to determine, can be used as a base, with all other cost areas given values in relation to these costs.

TC = (Material Cost) + (Equipment Cost) + (Graphics Costs) + (Labor Cost) + (Lost Product) + (Cost of Decreased Line Speeds)

Material Cost = Easily determined by individual companies
Equipment Cost = 1.4 x Material Cost
Graphics Cost = 0.1 x Material Cost
Labor Cost = 0.3 x Material Cost
Product Loss = Not predictable from this study
Cost of Decreased Line Speed = Not predicatable: Will vary widely depending on equipment & packaging style

The above cost equation could be used as a basis for calculating packaging costs associated with similar packaging legislation. Individual circumstances will vary and each company will want to adjust the above values to more accurately reflect their situation.

A more precise estimate might be possible after further study of this regulation. The industry should be asked about the amount of product lost due to tamper-resistant packaging legislation and decreased line speeds should be examined. Some research might also be done on why consumer product prices have increased up to 40% while manufacturing costs have increased much less.

NOTES

1. Board of Commissioners, Cook County, Illinois. "An Ordinance of the County of Cook Requiring That All O-T-C, Non-prescription Drugs and Medicines be Enclosed in Sealed Containers Prior to Being Sold Within Cook County". An ordinance proposed by Commissioner Bernard Carcy, October 4, 1982.

2. Arthur Stupay. "Tylenol Legacy: Surging Sales for Safe Seals." Time, November 1, 1982, p. 64.

3. Food and Drug Administration. "Tamper-Resistant Packaging Requirements; Certain Over-The-Counter Human Drugs and Cosmetic Products; Contact Lens Solutions and Tablets; Final Rules". Office of the Federal Register, Volume 47, No. 215, p. 50444.

4. Ibid. p. 50447.

5. Food and Drug Administration. 21 Code of Federal Regulations 200.50.

6. U.S. Department of Health, Education and Welfare, Public Health Service/Food and Drug Administration. "Grade A Pasteurized Milk Ordinance (1978 Recommendations)". p. 31.

7. Bureau of Alcohol, Tobacco and Firearms. 27 Code of Federal Regulations 19.663.

8. Food and Drug Administration. 47 FR 50450.

9. Ibid.

10. Ibid.

11. Food and Drug Administration. 21 CFR 211.501 and 21 CFR 211.502.

12. Food and Drug Administration. 47 FR 50450.

13. Food and Drug Administration. 48 FR 16660.

14. Ibid.

15. Consumer Product Safety Commission. "Poison Prevention Packaging Act of 1970 Regulations". 16 CFR 1700.

16. Stephanie Medlock. "Inside the Consumer's Mind: A Look at Anti-Tampering Devices." Focus Group - Headline Medlock, January 5, 1983, p. 7.

17. Ibid. p. 8.

18. Food and Drug Administration. 47 FR 50449.

19. "Drug Packaging Will Cost." The Detroit Free Press, 28 October 1982, p. 19A.

20. Arthur Stupay, "Tylenol Legacy: Surging Sales for Safe Seals." Time, November 1, 1982, p. 64.

21. Edmund A. Leonard. An Introduction to the Economics of Packaging. McGraw-Hill, New York, 1971, 124 p.

22. "FDA Tamper Rules Don't Protect Packagers from Liability Suits." Package Engineering, December 1982, p. 18.

23. Arthur Stupay. "Tylenol Legacy: Surging Sales for Safe Seals." Time, November 1, 1982, p. 64.

24. Edward R. Barnhart, Publisher. Physicians Desk Reference for Nonprescription Drugs. New Jersey Medical Economics Company, Inc., 1983, pp. 1-15.

25. Mildred Parten, Ph.D. Surveys, Polls and Samples: Practical Procedures. New York: Harper and Brothers, 1950, pp. 228-230.

APPENDIX A

LIST OF PRODUCTS AFFECTED BY CHILD-RESISTANT AND TAMPER-RESISTANT REGULATIONS

APPENDIX A

LIST OF PRODUCTS AFFECTED BY CHILD-RESISTANT AND TAMPER-RESISTANT REGULATIONS

Products Affected by Child-Resistant Packaging Regulation

1. Aspirin
2. Furniture polish
3. Methyl salicylate
4. Controlled drugs
5. Sodium and/or potassium hydroxide
6. Turpentine
7. Kindling and/or illuminating preparations
8. Methyl alcohol
9. Sulfuric acid
10. Prescription drugs
11. Ethylene glycol
12. Iron-containing drugs
13. Dietary supplements containing iron
14. Pesewed
15. Solvents for paint or other similar surface-coating materials
16. Acetaminophen

Products Affected by Tamper-Resistant Packaging Regulation

1. All oral drug products (except dentifrices)
2. Nasal drug products
3. Otic drug products
4. Ophthalmic drug products including contact lens tablets and solutions
5. Rectal drug products
6. Vaginal drug products
7. All oral and vaginal cosmetic products

APPENDIX B

21 CFR 211.132
TAMPER-RESISTANT PACKAGING REQUIREMENTS FOR OVER-THE-COUNTER HUMAN DRUG PRODUCTS

correctness before packaging operations, and documentation of such examination in the batch production record.

(d) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

§ 211.132 Tamper-resistant packaging requirements for over-the-counter human drug products.

(a) *General.* Because most over-the-counter (OTC) human drug products are not now packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of OTC drug products with health risks to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of OTC drug product packages. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-resistant packaging of OTC drug products that will improve the security of OTC drug packaging and help assure the safety and effectiveness of OTC drug products. An OTC drug product (except a dermatological, dentifrice, or insulin product) for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this section is adulterated under section 501 of the act or misbranded under section 502 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, or insulin product) for retail sale, shall package the product in a tamper-resistant package. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To prevent the substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design (e.g., an aerosol container) or by the use of an identifying characteristic. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of an OTC drug product covered by this section is required to contain a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing.

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this chapter and should be clearly identified on the envelope as a "Request for Exemption from Tamper-resistant Rule." The petition is required to contain the following:

(1) The name of the drug product or, if the petition seeks an exemption for a drug class, the name of the drug class, and a list of products within that class.

(2) The reasons that the drug product's compliance with the tamper-resistant packaging or labeling requirements of this section is unnecessary or cannot be achieved.

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product or drug class will be the subject of malicious adulteration.

(4) Other information justifying an exemption.

This information collection requirement has been approved by the Office of Management and Budget under number 0910-0149.

(e) *OTC drug products subject to approved new drug applications.* Holders of approved new drug applications for OTC drug products are required under § 314.8 (a) (4)(vi), (5)(xi), or (d)(5) of this chapter to provide for changes in packaging, and under § 314.8(a)(5)(xii) to provide for changes in labeling to comply with the requirements of this section.

(f) *Poison Prevention Packaging Act of 1970.* This section does not affect any requirements for "special packaging" as defined under § 310.3(1) of this chapter and required under the Poison Prevention Packaging Act of 1970.

(g) *Effective date.* OTC drug products, except dermatological, dentifrice, and insulin products, are required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or labeling requirement.

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on February 7, 1983 for each affected OTC drug product (except oral and vaginal tablets and vaginal and rectal suppositories) packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each OTC drug product that is an oral or vaginal tablet or a vaginal or rectal suppository packaged for retail sale on or after that date.

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected OTC drug product packaged for retail sale on or after that date.

(3) *Retail level effective date.* The tamper-resistant packaging requirement of paragraph (b) of this section is effective on February 6, 1984 for each affected OTC drug product held for sale on or after that date that was packaged for retail sale before May 5, 1983. This does not include the requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design. Products packaged for retail sale after May 5, 1983, are required to be in compliance with all aspects of the regulations without regard to the retail level effective date.

(Secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371))

[47 FR 50449, Nov. 5, 1982; 48 FR 1707, Jan. 14, 1983]

EFFECTIVE DATE NOTE: Section 211.132 was added at 47 FR 50449, Nov. 5, 1982. For information regarding effective dates see paragraph (g) of this section.

§ 211.134 Drug product inspection.

(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label.

(b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling.

(c) Results of these examinations shall be recorded in the batch production or control records.

§ 211.137 Expiration dating.

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

APPENDIX C

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SUPPLEMENTAL APPLICATIONS

APPENDIX C

(v) Assure that the drug dosage form and components will comply with the specifications and tests described in an official compendium, if such article is recognized therein, or, if not listed or if the article differs from the compendium drug, that the specifications and tests applied to the drug and its components are adequate to assure their identity, strength, quality, and purity.

(vi) Outline the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of the drug.

(2) Labeling that is in accord with the labeling conditions described in the finding that an abbreviated new drug application is sufficient.

(3) If the drug finding so specifies for the formulation intended for marketing, data adequate to assure the biological availability of the drug. For preparations claiming sustained action, timed-release, or other delayed or prolonged effect, such data should show that the drug is available at a rate of release that will be safe and effective.

(4) Any information available to the applicant, including preclinical or clinical data developed by the applicant or by other persons on behalf of the applicant, on adverse effects of the drug that is not reflected in the labeling.

(5) Additional information that may be required for the approval of the application as specified in a written communication from the Food and Drug Administration.

(6) An environmental impact analysis report analyzing the environmental impact of the manufacturing process and ultimate use or consumption of the drug pursuant to § 25.1 of this chapter.

(7) Statements contained in the application regarding each clinical investigation involving human subjects, that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in Part 50 of this chapter.

(8) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

(9) The signature of the applicant or responsible official or agent on a completed Form FD-356H.

(Secs. 201(p), 502, 505, 701(a), 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055 (21 U.S.C. 321(p), 352, 355, 371(a)))

[48 FR 2755, Jan. 21, 1983]

§ 314.6 Amended applications.

The applicant may submit an amendment to an application that is pending, but in the case of a substantive amendment, the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

§ 314.7 Withdrawal of applications without prejudice.

The applicant may at any time withdraw his pending application from consideration as a new-drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The application itself will be retained by the Food and Drug Administration although it is considered withdrawn, but the applicant shall be furnished a copy at cost, on request.

§ 314.8 Supplemental applications.

(a)(1) After an application is approved, a supplemental application may propose changes. A supplemental application may omit statements made in the approved application concern-

ing which no change is proposed. Each supplemental application shall include up-to-date reports of any of the kinds of information required by § 310.300(a) of this chapter that has not previously been submitted as part of the application, including such submission under the records and reports requirements of § 310.300 of this chapter or § 310.302 of this chapter. A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 25.1 of this chapter.

(2) A supplemental application should be submitted for any change beyond the variations provided for in the application (including changes in the scale of production, such as from pilot-plant to production batch), that may alter the conditions of use, the labeling, the safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, or controls to preserve them.

(3) Any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application unless the parts of the labeling furnishing directions, warnings, and information for use of the drug are the same in language and emphasis as labeling approved or permitted, and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(4) The supplemental application shall be submitted as follows: A communication proposing a change in a new-drug application should provide for no more than one of the following kinds of changes:

(i) Revision in labeling; such as, updating information pertaining to effects, dosages, and side effects and contraindications, which includes information headed side effects, warnings, precautions, and contraindications.

(ii) Addition of claim.

(iii) Revision in manufacturing or control procedures; for example, changes in components, compositions, method of manufacture, analytical control procedures, package or tablet size, etc.

(iv) Change in manufacturing facilities.

(v) Provision for outside firm to participate in the preparation, distribution, or packaging of a new drug (new distributor, packer, supplier, manufacturer, etc.); one firm per submission.

(vi) A change in container to provide for "special packaging" as defined in § 310.3(l) of this chapter pursuant to the requirements of regulations under the Poison Prevention Packaging Act of 1970 or to provide for tamper-resistant packaging under § 211.132 of this chapter. The mailing cover and supplement shall be plainly marked "Special Container Packaging Supplement."

Any number of changes may be submitted at any one time; but if they fall into different categories as listed in paragraph (a)(4)(i) through (vi) of this section, the proposed changes should be covered by separate communications. Where, however, a change necessitates an "overlap" in categories, it should be submitted in a single communication. For example, a change in tablet potency would require other changes such as in components, composition, and labeling and should be submitted in a single communication.

(5) The following changes may be placed into effect without the approval of a supplemental application if such change is fully described in the next periodic report required under § 310.300(b)(4) of this chapter or § 310.302(e) of this chapter or, when such a report is not required, in a written communication to the Food and Drug Administration within 60 days of the effective date of the change(s). This does not apply to a change proposed because of any mixup or any bacteriological or significant chemical, physical, or other change or deterioration in the drug or any failure of one or more distributed batches of the drug to meet its specifications.

(i) A different container size for solid oral dosage forms where container and closure are of the same materials as those provided for in the approved application.

(ii) Change in personnel not involving new facilities.

(iii) Change in equipment that does not alter the method of manufacture of a new drug substance or dosage form of a new drug.

(iv) Change from one commercial batch size to another without any change in manufacturing procedure.

(v) Change to more stringent specification without altering the method described in the approved application.

(vi) Inclusion of additional specifications and methods without deletion of those described in the approved application.

(vii) Alteration of specifications or methods for inactive ingredients to bring them into compliance with new or revised specifications or methods in an official compendium.

(viii) Initiation of a product identification coding system.

(ix) Addition to labeling of a reasonable expiration date, where none was previously used, with related conditions of drug storage when appropriate, except when there is evidence that there has been a significant deterioration of the drug under marketing conditions which necessitates the immediate submission of a report under the provisions of § 310.300(b)(1) of this chapter. The report or written communication describing such change in labeling should include stability data justifying the expiration date and recommended conditions of storage.

(x) Change from paper labels to direct printing on glass containers without a change in text.

(xi) Changes which provide for "special packaging" as defined in § 310.3(l) of this chapter which are in the form of an "overcap" to the existing closure of a container without any other changes in the container/closure system or provide for tamper-resistant packaging under § 211.132 of this chapter. The report or written communication shall contain information as to the manufacturer of the safety closure and any identification applied to such closure.

(xii) Addition to the labeling of such statements as required by the Poison Prevention Act of 1970 or regulations promulgated thereunder or required for tamper-resistant packaging under § 211.132 of this chapter.

(xiii) Change in the label to provide for a statement directed to the pharmacist specifying the type(s) of container(s) to be used in dispensing the drug to maintain its identity, strength, quality, and purity.

(xiv) Change in distributor. The report or written communication shall contain the names of all new distributors that have been added since the last periodic report. Each copy of the report shall contain two copies of the new distributor's printed label showing the drug product's trade and established name, and its strength and dosage form. If a drug product is also distributed in a strength other than the one shown on the submitted label the report shall specify the additional strength. This section applies only if the new distributor's labeling is the same as the labeling provided for in the approved new drug application, except for the trade name of the drug product and the distributor's name. If there are further deviations from the labeling provided for in the approved new drug application, the provisions of paragraphs (a) (1) through (4) of this section apply. "Distributor", as used in this section, means the person or firm whose name appears on the label of the drug product as its distributor, but does not include a person or firm who, in addition to distributing the drug product, also repackages or relabels it. For purposes of maintaining records and submitting reports under the requirements of § 310.300 or § 310.302 of this chapter, a distributor as used in this section shall be considered an "applicant" within the meaning of § 310.300(g) of this chapter.

(b) When necessary, for the safety or effectiveness of the drug, a supplemental application shall specify a period of time within which the proposed change will be made.

(c) If a material change is made in the components, composition, manufacturing methods, facilities or controls, or in the labeling or advertising from the representations in an approved application for a new drug (except changes conforming to the conditions set forth in paragraphs (a) (5) and (6) and/or paragraphs (d), (e),

(f), and (g) of this section) and the drug is marketed before a supplement is approved for such change, approval of the application may be suspended or withdrawn as provided in section 505(e) of the act.

(d) Changes of the following kinds proposed in supplemental new-drug applications should be placed into effect at the earliest possible time:

(1) The addition to package labeling, promotional labeling, and prescription drug advertising of additional warning, contraindication, side-effect, and precaution information.

(2) The deletion from package labeling, promotional labeling, and drug advertising of false, misleading, or unsupported indications for use or claims for effectiveness.

(3) Changes in the methods, facilities, or controls used for the manufacture, processing, packing, or holding of the drug (other than utilization of establishments not covered by the approval that is in effect) that give increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess.

(4) The addition to the package labeling, promotional labeling, or prescription drug advertisements of information adequate to inform the prescriber of a drug of the findings of a panel of the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, with respect to any claim in the labeling evaluated other than "effective," in accordance with § 201.200 of this chapter.

(5) Changes which provide for "special packaging" as defined in § 310.3(1) of this chapter other than the use of an additional closure as provided for in paragraph (a)(5)(xi) of this section, where the composition of the container, the torque (tightness) of the container, and the composition of the closure component in contact with the drug (cap liner or innerseal) remain the same as provided in the approved new drug application or provide for tamper-resistant packaging under § 211.132 of this chapter.Each such supplement shall include:

(i) A representative market package and any identification applied to such package and

(ii) Preliminary data showing that the package is satisfactory as a barrier to moisture and gas transmission or 3 months accelerated stability data which include assay data, as well as data on other significant properties of the product at room temperature and at exaggerated temperatures and conditions of high humidity. In the event that the sole change in package is in the composition or configuration of the cap (outer shell not in contact with the drug) other data or information which demonstrate the adequacy of the liner alone to serve as an effective barrier will be acceptable in lieu of moisture and gas transmission or accelerated stability data. For any changes instituted under the provisions of this paragraph, the applicant shall submit a written commitment that he will test the stability of initially marketed batches of the drug; submit the information at intervals of 3 months beginning with the date of initial packaging during the first year following such date, at intervals of 6 months during the second year following such date, and at yearly intervals thereafter for as long as necessary to support or establish an assigned expiration date, unless otherwise ordered in a written communication by the Food and Drug Administration; and withdraw from the market any batch found to fall outside the approved specifications for the drug or discuss the deviation with the Food and Drug Administration if the applicant believes the deviation is not significant.

(e) It will be the policy of the Food and Drug Administration to take no action against a drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed in effect by the applicant prior to his receipt of a written notice of approval of the supplemental new-drug application: *Provided*, That all the following conditions are met:

(1) The supplemental new-drug application providing a full explanation of the basis for the changes has been submitted, plainly marked on the mailing cover and on the supplement

"Special new-drug application supplement—Changes being effected."

(2) The applicant specifically informs the Food and Drug Administration of the date on which such changes are being effected, and submits to the Administration 12 printed copies of any revised labeling to be placed in use, identified with the new-drug application number.

(3) All promotional labeling and all drug advertising are promptly revised consistent with the changes made in the labeling on or within the drug package.

(f) When a supplemental application proposes changes only of the kinds of described in paragraph (d) of this section, and the applicant informs the Food and Drug Administration that the changes are being put into effect, such notification will be regarded as an agreement by the applicant to an extension of the time for formal action on the application.

(g) In addition to changes as permitted by paragraphs (d) and (e) of this section, an applicant may place into effect changes proposed in a supplement to a new-drug application that became effective prior to October 10, 1962, upon written notification from the Food and Drug Administration that such action is permitted, without approval of the supplemental application, pending the completion of the review of the effectiveness of such drug by the National Academy of Sciences—National Research Council and a determination as to whether there are grounds for refusing approval under section 505(d) of the act or for invoking section 505(e). It will be the policy of the Food and Drug Administration to take no action against a drug or an applicant solely because changes that have been permitted in a written communication are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental new-drug application.

(h) Except as provided in paragraphs (e) and (g) of this section, no provision of this section shall limit the authority of the Secretary or of the Commissioner to suspend or withdraw approval of a new-drug application in accord with the provisions of section 505(e) of the act or to initiate any other regulatory proceedings with respect to a drug or applicant under provisions of the act.

(i) Changes from the conditions of an approved new-drug application in accord with the provisions of paragraphs (d), (e), and (g) of this section are permitted on the basis of a temporary deferral of final action on the supplemental application under the provisions of section 505(c), (d), or (e) of the act.

(j) When an applicant receives written notification from the Food and Drug Administration, under the provisions of paragraph (g) of this section, that he may place into effect changes proposed in a supplemental application without approval of the supplemental application, he may within 30 days submit a written request that the Food and Drug Administration process the supplemental application. In such case, the change shall not be put into effect until approved. Within 180 days of the receipt of such written request, the Food and Drug Administration will approve the supplemental application or furnish notice of an opportunity for a hearing under the provisions of section 505(d) or (e), or both, of the act on proposals to refuse the supplemental application or to withdraw approval of the application and supplements thereto.

(k) A supplement to an application that became effective prior to October 10, 1962, may include a written statement to the effect that a temporary deferral of final action under the provisions of paragraphs (d), (e), or (g) of this section is unacceptable to the applicant and that the applicant requests action as provided in section 505(c) of the act. Final action on such supplemental applications will be expedited in accord with applicable provisions of section 505 of the act and regulations in this part and Part 310 of this chapter. In such cases, if the applicant places into effect any of the proposed changes prior to his receipt of a written notice of approval of the supplemental new-drug application, such action may be regarded by the Food and Drug Administration as a basis for invoking the provisions of section 505(e)(4) of the act; that is, the

applicant may be furnished notice of an opportunity for a hearing on a proposal to withdraw approval of the application on the grounds that the application contains an untrue statement of a material fact related to the changes from the conditions approved in the application.

(l) A supplemental application that contains nonclinical laboratory studies shall include, with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

(m) [Reserved]

(n) A supplemental application that contains clinical investigations involving human subjects shall include statements by the applicant regarding each such investigation, that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in Part 50 of this chapter.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360l); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; 42 U.S.C. 216, 262 263b-263n; Secs. 301, 502, 505, 701(a), 52 Stat. 1042-1043 as amended, 1049-1053 as amended, 1055 (21 U.S.C. 331, 352, 355, 371(a)); Secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371))

[39 FR 11718, Mar. 29, 1974, as amended at 39 FR 20484, June 11, 1974; 39 FR 27795, Aug. 1, 1974; 40 FR 13496, Mar. 27, 1975; 42 FR 15674, Mar. 22, 1977; 43 FR 37989, Aug. 25, 1978; 43 FR 60022, Dec. 22, 1978; 45 FR 25777, Apr. 15, 1980; 46 FR 8954, Jan. 27, 1981; 46 FR 21360, Apr. 10, 1981; 46 FR 32017, June 19, 1979; 47 FR 50450, Nov. 5, 1980]

§ 314.9 Insufficient information in application.

(a) The information contained in an application may be insufficient to determine whether a drug is safe or effective in use if it fails to include (among other things) a statement showing whether the drug is to be limited to prescription sale and exempt under section 502(f)(1) of the act from the requirement that its labeling bear adequate directions for use. If the drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with § 201.100 or § 201.105 of this chapter, and information concerning hazards, contraindications, side effects, and precautions, relevant with respect to any uses for which the drug is commonly prescribed.

(2) The application fails to show that the labeling and advertising of the drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for use of the drug will contain substantially the same information for use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application, in accordance with § 201.100 or § 201.105 of this chapter.

(b) The information contained in an application will be considered insufficient to determine whether a drug is

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FOR COSMETIC PRODUCTS

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toxic effects in the lungs and other organs of experimental animals. When used in aerosol form, some zirconium will reach the deep portions of the lungs of users. The lung is an organ, like skin, subject to the development of granulomas. Unlike the skin, the lung will not reveal the presence of granulomatous changes until they have become advanced and, in some cases, permanent. It is the view of the Commissioner that zirconium is a deleterious substance that may render any cosmetic aerosol product that contains it injurious to users.

(b) Any aerosol cosmetic product containing zirconium is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any such cosmetic product introduced in interstate commerce after September 15, 1977 is subject to regulatory action.

(Sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355))

[42 FR 41376, Aug. 16, 1977]

§ 700.18 Use of chloroform as an ingredient in cosmetic products.

(a) Chloroform has been used as an ingredient in cosmetic products. Recent information has become available associating chloroform with carcinogenic effects in animals. Studies conducted by the National Cancer Institute have demonstrated that the oral administration of chloroform to mice and rats induced hepatocellular carcinomas (liver cancer) in mice and renal tumors in male rats. Scientific literature indicates that chloroform is absorbed from the gastrointestinal tract, through the respiratory system, and through the skin. The Commissioner concludes that, on the basis of these findings, chloroform is a deleterious substance which may render injurious to users any cosmetic product that contains chloroform as an ingredient.

(b) Any cosmetic product containing chloroform as an ingredient is adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act. Any cosmetic product containing chloroform in residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient, is not, for the purpose of this section, considered to contain chloroform as an ingredient.

[41 FR 26845, June 29, 1976]

§ 700.23 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in cosmetics as propellants in self-pressurized containers is prohibited as provided in § 2.125 of this chapter.

(Secs. 301, 402, 409, 501, 502, 505, 507, 512, 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1049-1053 as amended, 1055, 57 Stat. 463 as amended. 72 Stat. 1985-1788 as amended, 82 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b); sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332))

[43 FR 11317, Mar. 17, 1978]

§ 700.25 Tamper-resistant packaging requirements for cosmetic products.

(a) *General.* Because most cosmetic liquid oral hygiene products and vaginal products are not now packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of those cosmetic products with health risks to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of cosmetic product packages. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-resistant packaging of cosmetic liquid oral hygiene products or products used vaginally that will improve the packaging security and help assure the safety of those products. Such a cosmetic product for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this section is adulterated under section 601 of the act or misbranded under section 602 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages a cosmetic liquid oral hygiene product or vaginal product for retail sale shall package the product in a tamper-resistant package. A tamper-resistant package is one having an indicator or barrier to entry

which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To prevent the substitution of a tamper-resistant feature after tampering the indicator or barrier to entry is required to be distinctive by design (e.g., an aerosol container) or by the use of an identifying characteristic. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a cosmetic product covered by this section is required to contain a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing.

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this chapter and should be clearly identified on the envelope as a "Request for Exemption from Tamper-resistant Rule." The petition is required to contain the following:

(1) The name of the product.

(2) The reasons that the product's compliance with the tamper-resistant packaging or labeling requirements of this section is unnecessary or cannot be achieved.

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product will be the subject of malicious adulteration.

(4) Other information justifying an exemption.

This information collection requirement has been approved by the Office of Management and Budget under number 0910-0149.

(e) *Effective date.* Cosmetic products covered by this section are required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or labeling requirement.

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on Feburary 7, 1983 for each affected cosmetic product (except vaginal tablets) packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each cosmetic product that is a vaginal tablet packaged for retail sale on or after that date.

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected cosmetic product packaged for retail sale on or after that date.

(3) *Retail level effective date.* The tamper-resistant packaging requirement of paragraph (b) of this section is effective February 6, 1984 for each affected cosmetic product held for sale on or after that date that was packaged for retail sale before May 5, 1983. This does not include the requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design. Products packaged for retail sale after May 5, 1983, as required to be in compliance with all aspects of the regulations without regard to the retail level effective date.

(Secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982))

APPENDIX E

21 CFR 200.50

OPTHALMIC PREPARATIONS AND DISPENSERS

ered to be subject to certification as "drugs composed wholly or partly of insulin":

(1) Pancreas glands; and

(2) Materials prepared from pancreas glands, such as "salt cake" and "isoelectric precipitate," which materials must be subjected to further purification in order to meet the standards of purity established by Part 429 of this chapter.

(Sec. 506, 55 Stat. 851; 21 U.S.C. 356)

Subpart B—Manufacturing Procedures Affecting New Drug Status

§ 200.30 Sterilization of drugs by irradiation.

There is a current interest in the utilization of newly developed sources of radiation for the sterilization of drugs. Prior to the marketing of a drug sterilized by such means, it is necessary in the interest of protecting the public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. Accordingly, all drug products, including injections, ophthalmic solutions, surgical sutures, and surgical dressings sterilized by means of irradiation are regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An effective new-drug application pursuant to section 505 of the act is therefore a prerequisite to interstate shipment of such articles, except as provided by section 505(i).

(Secs. 201, 505, 52 Stat. 1040, as amended, 1052, as amended; 21 U.S.C. 321, 355)

§ 200.31 Timed release dosage forms.

(a) Many drugs are now being offered in dosage forms that are designed to release the active ingredients over a prolonged period. There is a possibility of unsafe overdosage if such products are improperly made and the active ingredients are released at one time or over too short a time interval. Any such dosage form that contains per dosage unit (for example, capsule or tablet), a quantity of active drug ingredients which is not generally recognized as safe for administration as a single dose under the conditions suggested in its labeling, is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(b) The fact that the labeling of this type of drug may claim delayed or prolonged release of all or some of the active ingredients does not affect the new-drug status of such articles. A new-drug application is required in any such case to demonstrate that the drug is in fact safe because it is properly made and controlled to release the total dose at a safe rate. It should be noted particularly that such dosage forms are regarded as new drugs even when the total daily dosage recommended in the labeling is generally recognized as safe. For example, a capsule containing 50 milligrams of pyrilamine maleate and 15 milligrams of phenylephrine hydrochloride, offered for sale without prescription, is regarded as a new drug for which the distributor should have an effective new-drug application, even though the directions call for taking no more than two capsules daily. While the daily intake under such directions is within the range regarded as safe for use in self-medication, the single dose is too high for such use unless the release of the drug is sufficiently prolonged. It is obvious that, in filing a new-drug application for such an article, particular attention should be given to data which establish that the active ingredients are released over a period of time, as represented in the labeling.

(Sec. 201(p), 52 Stat. 1042; 21 U.S.C. 321(p))

Subpart C—Requirements for Specific Classes of Drugs

§ 200.50 Ophthalmic preparations and dispensers.

(a)(1) Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use, including preparations for cleansing the eyes, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye.

(2) The Food and Drug Administration concludes that all such prepara-

tions, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe. In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (the act), and, further, may be deemed misbranded within the meaning of section 502(j) of the act. This ruling is extended to affect all preparations for ophthalmic use. By this regulation, this ruling is applicable to ophthalmic preparations that are regulated as drugs. By the regulation in § 800.10 of this chapter, this ruling is applicable to ophthalmic preparations that are regulated as medical devices.

(3) The containers of ophthalmic preparations shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. The packaging and labeling of ophthalmic preparations that are over-the-counter drugs shall also comply with § 211.132 of this chapter on tamper-resistant packaging requirements.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should:

(1) Contain one or more suitable and harmless substances that will inhibit the growth of microorganisms; or

(2) Be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings as to afford adequate protection and minimize the hazard of injury resulting from contamination during use.

(c) Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. These articles, which are regulated as drugs if packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

(Secs. 501, 502, 515, 521, 701, 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 552-559, 574 (21 U.S.C. 351, 352, 360e, 360k, 371))

[40 FR 13996, Mar. 27, 1975, as amended at 48 FR 50455, Nov. 5, 1982]

EFFECTIVE DATE NOTE: Section 200.50(a)(3) was revised at 47 FR 50455, Nov. 5, 1982. For information regarding effective dates, see § 211.132. Paragraph (a)(3) published at 40 FR 13996, Mar. 27, 1975, and set forth below is currently effective.

§ 200.50 Ophthalmic preparations and dispensers.

(a)(1)* * *

(3) The containers of ophthalmic preparations shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. To provide time for validation of sterility tests and changes to sterile production procedures, this ruling will be effective for nonantibiotic ophthalmic ointment preparations recognized in the official compendia (U.S.P. and N.F.) on the dates specified in such official compendia. For all other ophthalmic ointments, this ruling will be effective 12 months after the date of publication in the FEDERAL REGISTER (10-28-72).

* * *

Subpart D—Suitability of Specific Drug Components

§ 200.100 Use of ox bile from condemned livers from slaughtered animals in the manufacture of drugs.

(a) Conferences have recently been held between members of the Department of Health and Human Services and representatives of the Agricultural Research Service, Department of Agriculture, concerning requests made to that agency for the release of ox bile from condemned livers of slaughtered animals for use in the manufacture of certain drugs.

(b) The Secretary of Health and Human Services has given careful consideration to this problem and has reached the conclusion that no hazard

APPENDIX F

21 CFR 800.12

CONTACT LENS SOLUTIONS AND TABLETS; TAMPER-RESISTANT PACKAGING

SUBCHAPTER H—MEDICAL DEVICES

PART 800—GENERAL

Subpart A—[Reserved]

Subpart B—Requirements for Specific Medical Devices

Subpart C—Administrative Practices and Procedures

Subpart A—[Reserved]

Subpart B—Requirements for Specific Medical Devices

§ 800.10 Contact lens solutions; sterility.

(a)(1) Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use, including contact lens solutions, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye.

(2) The Food and Drug Administration concludes that all such preparations, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe. In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (the act), and, further, may be deemed misbranded within the meaning of section 502(j) of the act. By this regulation, this ruling is applicable to all preparations for ophthalmic use that are regulated as medical devices, i.e., contact lens solutions. By the regulation in § 200.50 of this chapter, this ruling is applicable to ophthalmic preparations that are regulated as drugs.

(3) The containers shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. The packaging and labeling of these solutions shall also comply with § 800.12 on tamper-resistant packaging requirements.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should:

(1) Contain one or more suitable and harmless substances that will inhibit the growth of microorganisms; or

(2) Be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings as to afford adequate protection and minimize the hazard of injury resulting from contamination during use.

(c) Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. These articles, which are regulated as medical devices unless packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

(Secs. 201(n), 501, 502, 515, 521, 701, 52 Stat. 1041 as amended, 1049–1051 as amended, 1055–1056 as amended, 90 Stat. 552–559, 574 (21 U.S.C. 321(n), 351, 352, 360e, 360k, 371))

[47 FR 50455, Nov. 5, 1982]

§ 800.12 Contact lens solutions and tablets; tamper-resistant packaging.

(a) *General.* Unless contact lens solutions used, for example, to clean, disinfect, wet, lubricate, rinse, soak, or store contact lenses and salt tablets to be used to make any such solutions are packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of these products with risks both to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of the packages of over-the-counter (OTC) health

care products. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national standard for tamper-resistant packaging of those OTC products vulnerable to malicious adulteration that will improve the security of OTC packaging and help assure the safety and effectiveness of the products contained therein. A contact lens solution or tablet to be used to make such a solution for retail sale that is not packaged in a tamper-resistant package and labeled in accordance with this section is adulterated under section 501 of the act or misbranded under section 502 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages for retail sale a product regulated as a medical device that is a solution intended for use with contact lenses, e.g., for cleaning, disinfecting, wetting, lubricating, rinsing, soaking, or storing contact lenses or tablets to be used to make any such solution shall package the product in a tamper-resistant package. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To prevent the substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a product covered by this section is required to contain a statement that is prominently placed so that consumers are alerted to the tamper-resistant feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing.

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this chapter and should be clearly identified on the envelope as a "Request for Exemption from Tamper-resistant Rule." A petition for an exemption from a requirement of this section is required to contain the same kind of information about the product as is specified for OTC drugs in § 211.132(d) of this chapter. This information collection requirement has been approved by the Office of Management and Budget under number 0910-0150.

(e) *Products subject to approved premarket approval applications.* Holders of approved premarket approval applications for products subject to this section are required to submit supplements to provide for changes in packaging to comply with the requirement of paragraph (b) of this section unless these changes do not affect the composition of the container, the torque (tightness) of the container, or the composition of the closure component in contact with the contents (cap liner or innerseal) as these features are described in the approved premarket approval application. Any supplemental premarket approval application under this paragraph is required to include data sufficient to show that these changes do not adversely affect the product.

(f) *Effective date.* Each product subject to this section is required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or labeling requirement:

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on February 7, 1983 for each contact lens solution packaged for retail sale on or after that date, except for the requirement in

APPENDIX G

SURVEY COVER LETTER

APPENDIX G

May 3, 1983

NAME
COMPANY NAME
ADDRESS

Dear Sir;

We are currently involved in assessing the economic aspects of the new FDA regulation requiring tamper-resistant packages for over-the-counter drug products. We would like to ask your help in doing this study.

This regulation will affect all areas of the packaging industry, including machine manufacturers, material suppliers, printers and over-the counter drug packagers with an impact similar to the Child-resistant packaging regulation of 1970. It is important that an unbiased assessment of the regulation's effects on the industry be conducted so that such information will be available for future regulatory and economic considerations.

In order to accomplish our assessment we need the cooperation of the packaging industry. You can help by completing the enclosed questionnaire. We are trying to get specific economic information about what costs you incured inorder to comply with the new regulation, and what specifically caused the increased costs. Please check the most appropriate response for each question; if none of the responses provided accurately reflects your situation, we would appreciate your best estimate, an approximate dollar range or written explanation. Please associate any expected costs with the time period beginning with the issue date of the regulation (November 5, 1982) and ending one year later. Any additional comments you have are more than welcome. Please return your completed questionnaire in the enclosed, stamped envelope. We would like all questionnaires returned, whether completed or not, by June 3, 1983.

The results of this survey will be kept completely confidential; no mention of company name, products or other identifying factors will be made in our reports, summaries or references.

If you have any questions please contact Valerie Hamm at PHONE NUMBER. Thank you for your cooperation and contribution to this study.

Sincerely,

Valerie Hamm

APPENDIX H

SURVEY - PHARMACEUTICAL COMPANIES

APPENDIX H

DIRECTIONS: IF POSSIBLE, PLEASE HAVE THIS FORM COMPLETED BY A MEMBER OF YOUR COMPANY WHO IS RESPONSIBLE FOR TAMPER-RESISTANT PACKAGING.

Please check the appropriate response or complete with short answers. If any multiple choice question would be more accurately completed with a short answer, please feel free to do so. Remember, your answers will be kept strictly confidential.

Please return this questionnaire, whether completed or not, by June 3, 1983.

SECTION 1: GENERAL INFORMATION

1. Your area of responsibility: (CHECK ONE)

_____Packaging
_____Sales/Marketing
_____Purchasing
_____Corporate Management
_____Regulatory Affairs
_____Quality Control
_____Production/Manufacturing
_____Project Engineering
_____R&D
_____Other (please specify) _____

2. Nature of Company: (CHECK ONE)

_____Machinery Supplier
_____Materials supplier
_____Closure Supplier
_____Other (please specify) _____
_____Drug Manufacturer
_____Food Manufacturer
_____Container Supplier

3. Is your company: (CHECK ONE)

_____Local
_____Regional
_____National
_____International

4. Annual sales for your last fiscal year: (for your division involved in tamper-resistant packaging: please indicate if the dollar value you check below is for more than your division only)

_____Unknown
_____$0 to $5 million
_____$5 million to $10 million
_____$10 million to $50 million
_____$50 million to $100 million
_____$100 million to $250 million
_____$250 million to $500 million
_____$500 million to $750 million
_____$750 million to $1 billion
_____$1 billion and up

5. Which of your products (generic type) were affected by the tamper-resistant regulation? (PLEASE LIST)

PRODUCT TYPE

1._____
2._____
3._____
4._____
5._____
6._____
7._____
8._____

* NOTE: For the remaining questions which ask you to refer to your affected products, please feel free to refer to them by the numbers used above if that is easier for you.

6. Did or will each product in question 5 require a change in Packaging in order to comply with the new regulation? (PLEASE CHECK)

_____YES (go to 6B)

_____NO (go to 6A)

A) Please list below the products from question #5 that will not require a package change AND describe their packages. (i.e. the package must already comply with the regulation)

PRODUCT	CURRENT PACKAGE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

6B) STEP 1: Please read the following list of tamper-resistant materials and devices.

1. Film wrappers	8. Bottle seals
2. Blister or strip packs	9. Tape seals
3. Bubble packs	10. Breakable seals
4. Shrink seals or bands	11. Sealed tubes
5. Sealed cartons	12. Aerosol containers
6. Adhesive	13. Other (please specify)
7. Foil, paper of plastic pouches	_____

STEP 2: In column 1 below, please list all products from question #5 that did or will require package changes in order to comply with the regulation.

STEP 3: In column 2 below, list by number, all materials and devices from the above list being used for each particular product in order to make them tamper-resistant.

STEP 4: In column 3, list how much it cost per package to add the above materials to each product. Please try to list such that we are able to determine which costs are associated with which material or device. (SEE EXAMPLE)

	(1) PRODUCT	(2) LIST ALL MATERIALS FROM ABOVE LIST BEING USED FOR EACH PRODUCT	(3) COST PER PACKAGE
<EXAMPLE:	Product #4	Materials #4,#8, and #5	$.01, $.02, $.005 >
<			(total $.035/pkg) >
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
8.	_____	_____	_____

7. What new equipment/machinery did or will you purchase in order to produce complying packages? Please CHECK equipment type purchased, indicate how many were bought, the cost for each machine, and the cost you expect them to add per package.

EQUIPMENT PURCHASED	NUMBER PURCHASED	COST EACH	COST PER PACKAGE
A)____None purchased			
B)___Band applicators	_____	_____	_____
C)___Shrink tunnels	_____	_____	_____
D)___Shrink wrappers	_____	_____	_____
E)___Cartoner	_____	_____	_____
F)____Adhesive attachments for cartoners	_____	_____	_____
G)___Cappers	_____	_____	_____
H)___Tube formers	_____	_____	_____
I)___Blister/bubble formers	_____	_____	_____
J)___Pouch formers	_____	_____	_____
K)___Tape applicators	_____	_____	_____
L)___Induction sealers	_____	_____	_____
M)___Other(please specify)_____	_____	_____	_____

8. Has there been or do you expect a change in line speeds due to your required package changes? (PLEASE CHECK AND COMPLETE)

_____No change

_____Yes: Line speeds decreased by _____ percent.

_____Yes: Line speeds increased by _____ percent.

9. What labor changes were or will be necessary due to this tamper-resistant regulation? (PLEASE CHECK)

_____No change

_____Decrease-Total cost $_____Amortized over _____pkgs.

_____Increase-Total cost $_____Amortized over _____pkgs.

10. Did or will you experience additional costs for graphics/artwork inorder to produce complying tamper-resistant packages? (CHECK)

_____ YES _____ NO

a) IF YES: Please indicate which product required the graphics change and the cost per package.

PRODUCT	COST PER PACKAGE
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____

11. What was the main factor in determining which tamper-resistant system(s) your company chose? (CHECK ONE)

_____Most effective option
_____Lowest cost option
_____Most readily available materials/system (time)
_____Most compatable with existing packaging
_____Most compatable with existing machinery system
_____Other (specify)_____

12. If you have changed your advertising because of this regulation, please indicate how much you expect this to cost you for the first year.(CHECK ONE AND COMPLETE)

_____No change
_____Decrease-Total Cost $_____ Amortized over _____pkgs.
_____Increase-Total Cost $_____ Amortized over _____pkgs.

13. The new regulation requires that all affected products sold at the retail level on or after February 6, 1984, be in tamper-resistant containers. If your company still has non-tamper-resistant containers on the retail shelves at that time, what do you plan to do with the non-complying product? (CHECK ONE AND INDICATE EXPECTED LOSSES)

a) _____ Expect most non-complying packages to be sold by that time.
b) _____ Plan to recall and repackage product in Tamper-resistant packages.
c) _____ Plan to recall and discard product
d) _____ Plan to have retailers dispose of product and give them credit for lost product.

e) _____ Other plans for non-complying packages
(please specify)_____

EXPECTED LOSSES:

Cost of Repackaging	$_____
Number of packages re-filled	_____
Transportation costs	$_____
Product loss in dollars	$_____
Number of packages lost	_____
Other expected losses	_____
	_____

14. How did or how do you expect this regulation to affect your company's sales volume for this first year beginning with the issue date(Nov. 5, 1982) of the tamper-resistant regulation? (CHECK ONE AND COMPLETE)

_____No change
_____Decrease-dollar value $_____ Number of packages_____
_____Increase-Dollar value $_____ Number of packages_____

15. Do you expect your additional costs caused by this regulation to affect the retail price of the product?

_____YES; increased cost per package $_____

_____NO; cost per package we will absorb $_____

16. Please note any additional costs or changes due to this tamper-resistant regulation which we may have over looked.

17. COMMENTS PLEASE:

Thank You for your cooperation and help in this study.

PLEASE RETURN BY JUNE 3, 1983.

APPENDIX I

SURVEY -SUPPLIER COMPANIES

DIRECTIONS: IF POSSIBLE, PLEASE HAVE THIS FORM COMPLETED BY A MEMBER OF YOUR COMPANY WHO IS RESPONSIBLE FOR TAMPER-RESISTANT PACKAGING.

Please check the appropriate response or complete with short answers. If any multiple choice question would be more accurately completed with a short answer, please feel free to do so. Remember, your answers will be kept strictly confidential.

Please return this questionnaire, whether completed or not, by June 3, 1983.

SECTION 1: GENERAL INFORMATION

1. Your area of responsibility: (CHECK ONE)

_____Packaging
_____Sales/Marketing
_____Purchasing
_____Corporate Management
_____Regulatory Affairs
_____Quality Control
_____Production/Manufacturing
_____Project Engineering
_____R&D
_____Other (please specify) _____

2. Nature of Company: (CHECK ONE)

_____Machinery Supplier
_____Materials supplier
_____Closure Supplier
_____Other (please specify) _____
_____Drug Manufacturer
_____Food Manufacturer
_____Container Supplier

3. Is your company: (CHECK ONE)

_____Local
_____Regional
_____National
_____International

4. Annual sales for your divisions involved in tamper-resistant packaging (last fiscal year).

_____Unknown
_____$0 to $5 million
_____$5 million to $10 million
_____$10 million to $50 million
_____$50 million to $100 million
_____$100 million to $250 million
_____$250 million to $500 million
_____$500 million to $750 million
_____$750 million to $1 billion
_____$1 billion and up

5. What materials or devices do you supply that are now being used to make tamper-resistant packages? (PLEASE CHECK)

A. _____none,(if you supply equipment go to question #6)

B. _____film wrappers

C. _____Blister or strip packs

D. _____Bubble packs

E. _____Shrink seals or bands

F. _____Sealed cartons

G. _____Adhesive

H. _____Foil, paper or plastic pouches

I. _____Bottle seals

J. _____Tape seals

K. _____Breakable caps

L. _____Sealed tubes

M. _____Aerosol containers

N. _____Other(please specify) _____

6. What machines do you supply that are now being used to produce tamper-resistant packages?

A) _____None

B) _____Band applicators

C) _____Shrink tunnels

D) _____Shrink wrappers

E) _____Cartoners

F) _____Adhesive attachments for cartoners

G) _____Cappers

H) _____Tube formers

I) _____Blister/bubble formers

J) _____Pouch formers

K) _____Tape applicators

L) _____Induction sealers

M) _____Other (please specify)_____

7. Did or will you increase production capacity to meet the demand for your tamper-resistant materials, devices, or forming/application equipment? (PLEASE CHECK)

_____YES _____NO

A) If yes: Did you increase capacity by purchasing new machinery/equipment?
(PLEASE LIST EQUIPMENT, NUMBER PURCHASED AND COST)

_____ Check here if none was purchased

MACHINE	NUMBER PURCHASED	COST EACH
1._____	_____	_____
2._____	_____	_____
3._____	_____	_____
4._____	_____	_____
5._____	_____	_____
6._____	_____	_____
7._____	_____	_____

8. What labor changes were or will be necessary at your company due to this tamper-resistant regulation? (PLEASE CHECK)

_____No change
_____Decrease in labor hours-Total Savings $_____
_____Increase in labor hours-Total Cost $_____

9. What Changes have you had or do you expect to have in Advertising costs?
(From November 5, 1982 to November 6, 1983)
CHECK ONE AND COMPLETE

_____No change
_____Decrease-Total Cost $_____
_____Increase-Total Cost $_____

10. How did or how do you expect this regulation to affect your company's sales volume? (CHECK ONE AND COMPLETE)

_____No change in sales volume expected
_____Decreased volume: Dollar value $_____
_____Increased volume: Dollar value $_____

11. Do you expect your additional costs caused by this regulation to be passed on to your customers?

_____We did not incur additional costs due to this regulation.
_____YES we will pass costs to our customers
_____NO we will absorb additional cost

12. Please note any additional costs or changes due to this tamper-resistant regulation which we may have over looked.

13. COMMENTS PLEASE:

Thank You for your cooperation and help in this study.
PLEASE RETURN BY JUNE 3, 1983.

APPENDIX J

DATA - PHARMACEUTICAL COMPANIES

APPENDIX J

DATA - PHARMACEUTICAL COMPANIES*

SECTION 1: GENERAL INFORMATION

1. Your area or responsibility: (CHECK ONE)

13	Packaging	0	Quality Control
0	Sales/Marketing	1	Production/Manufacturing
1	Purchasing	0	Project Engineering
0	Corporate Management	1	R&D
0	Regulatory Affairs	1	Other (please specify) - Engineering/Package Dev.

2. Nature of Company: (CHECK ONE)

0	Machinery Supplier	15	Drug Manufacturer
1	Materials Supplier	0	Food Manufacturer
0	Closure Supplier	1	Container Supplier
1	Other (Please specify) - Medical device manufacturer		

3. Is your company: (CHECK ONE)

0	Local	1	National
0	Regional	13	International

4. Annual sales for your last fiscal year: (for your division involved in tamper-resistant packaging: please indicate if the dollar value you check below is for more than your division only)

1	Unknown	3	$100 million to $250 million
0	$0 to $5 million	5	$250 million to $500 million
0	$5 million to $10 million	0	$500 million to $750 million
1	$10 million to $50 million	1	$750 million to $1 billion
0	$50 million to $100 million	5	$1 billion and up

*20 usable surveys were returned. Many surveys were not completely filled out.

5. Which of your products (generic type) were affected by the tamper-resistant regulation? (PLEASE LIST)

NOTE: Of the 20 usable surveys, 12 companies completely answered this question.

PRODUCT TYPE

1. Cough syrup; cold tablets
2. Rectal ointment and suppository; nasal solutions; nasal spray
3. Vitamin drops; vitamin tablets
4. Dry products: capsules, tablets, powders; liquid products; creams and ointments; suppositories
5. Mouthwash; cough and cold liquid products; tablets and capsules; lozenges
6. Hay fever inhibitor; motion sickness inhibitor; diarrhea reliever
7. Cough/Cold tablets, capsules and liquids; analgesics; diet products
8. Aspirin (3 products); over-the-counter liquids (6 products); over-the-counter (labelled as foods -- 20 products)
9. Antacids - liquids and tablets; vitamins; laxatives - capsules and bulk powder; various other tablet products
10. Over-the-counter antacid liquid; O-T-C tablets; mouth irritant drops; ear wax control drops
11. Liquid cough preparations; O-T-C solid forms - capsules and tablets in bottles and blisters
12. Laxative - tablets, powder, liquid; cough preparation - liquid; cold medicine - capsules and tablets

6. Did or will each product in Question 5 require a change in Packaging in order to comply with the new regulation? (PLEASE CHECK)

__7__ YES (Go to 6A) __7__ NO (Go to 6B)

6A. Please list below the products from Question 5 that will not require a package change AND describe their packages. (i.e. the package must already comply with the regulation.

PRODUCT	CURRENT PACKAGE
1. Rectal suppository	Strip pack with distinguishable text
2. Vitamin tablets	Tack seal over lip
Vitamin drops	Wet band on cap
3. Cold tablets and capsules	Blister or bottle with innerseal
Cold liquid	Bottle and Child-Resistant closure
Analgesics	Bottle and C-R closure with innerseal
Diet products	Blister

6A. (Continued)

PRODUCT	CURRENT PACKAGE
4. Antacid liquid	Foil induction seal and cap
Antacid tablet	Foil pouch, strip packaging
Antacid tablet	Bottle with pressure-sensitive innerseal
5. Bottles of tablets and capsules	Seal under cap
Blister packs of capsules and tablets	Blister packs
6. Tablets	Blisters
7. Cold medicine tablets and capsules	Blisters

6B. STEP 1: Please read the following list of tamper-resistant materials and devices.

****

1. Film wrappers
2. Blister or strip packs
3. Bubble packs
4. Shrink seals or bands
5. Sealed cartons
6. Adhesive
7. Foil, paper or plastic pouches
8. Bottle seals
9. Tape seals
10. Breakable seals
11. Sealed tubes
12. Aerosol containers
13. Other (Please specify)

****

STEP 2: In Column 1 below, please list all products from Question 5 that did or will require package changes in order to comply with the regulation.

STEP 3: In Column 2 below, list by number, all materials and devices from the above list being used for each particular product in order to make them tamper-resistant.

STEP 4: In Column 3, list how much it cost per package to add the above materials to each product. Please try to list such that we are able to determine which costs are associated with which material or device.

PRODUCT	MATERIALS/DEVICES (BY NUMBER)	COST PER PACKAGE
1. Cough syrup	#4	$ .04 - .05
Cold tablets	#4	$ .04 - .05
2. Rectal ointment	#4, #11	$ .04, $.01
Nasal solutions	#4	.02
Nasal spray	#4	.05
3. Cold capsules, tablets, powders	#2, #4, #8	$ --
Liquid products	#4	--
Creams, ointments	#5, #11	--
Suppositories	#7	--
4. Mouthwash	#4	$ .015
Cough and cold liquid products	#4	.01
Tablets and capsules	#8	.005
Lozenges	#13 (graphics only)	<.0001
5. Hay fever inhibitor	#8	$ .004
Motion sickness inhibitor	#8	.004
Diarrhea reliever	#4	.006
6. Cough/cold liquids	#4	$ .03
7. Aspirin (3 products)	#8	$ .02
O-T-C liquids	#8, #9	.02, .01
O-T-C (labelled as foods)	#1, #2, #4, #7, #11	--

6B. (Continued)

PRODUCT		MATERIALS/DEVICES (BY NUMBER)	COST PER PACKAGE
8.	Antacids - liquids and tablets	#1, #4	$ .03, .02
	Vitamins	#4	.03
	Laxatives - capsules and bulk powder	#4	.03
	Various other tablet products	#4	.02
9.	O-T-C antacid liquid	#13 (graphics)	$ --
	O-T-C antacid tablets	#13 (graphics)	--
	Mouth irritant drops	#5, #13 (graphics)	$ .005, --
	Ear wax control drops	#5, #13 (graphics)	.005, --
10.	Liquid cough preparations	#5, #10	$ .007
11.	Laxative tablets	#9	$ .01
	Laxative powder	#4	.01
	Laxative liquid	#4	.01
	Cough preparations - liquid	#4	.01

7. What new equipment/machinery did or will you purchase in order to produce complying packages? Please CHECK equipment type purchased, indicate how many were bought, the cost for each machine, and the cost you expect them to add per package.

EQUIPMENT PURCHASED	NUMBER PURCHASED	COST EACH	COST PER PACKAGE
A) _3_ None purchased			
B) _5_ Band applicators			
1.	2	--	--
2.	5	3 @ $120,000 2 @ $ 35,000	--
3.	1	$ 75,000	--
4.	2	40,000	--
5.	4	200,000	$ .06 - .07 (1st year)
C) _6_ Shrink tunnels			
1.	1	$ 3,000	$ .002
2.	2	--	--
3.	4	3,000	--
4.	1	5,000	.0
5.	2	2,000	--
6.	4	5,000	.002
D) _1_ Shrink wrappers	2	$ 60,000	--
E) _0_ Cartoners			
F) _2_ Adhesive attachments for cartoners			
1.	1	$ 50,000	$ .005
2.	3	35,000	(7 year depreciation over 30 million packages/year)
G) _0_ Cappers			
H) _0_ Tube formers			
I) _0_ Blister/bubble formers			
J) _0_ Pouch formers			
K) _1_ Tape Applicators	1	$ 22,000	--
L) _2_ Induction Sealers			
1.	3	$ 19,000	--
2.	1	18,000	--
M) _2_ Other (Please specify)			
1. Labelers	14	$ 15,000	--
2. Labelers	6	25,000	--

8. Has there been or do you expect a change in line speeds due to your required package changes? (PLEASE CHECK AND COMPLETE)

__6__ No change

__6__ YES: Line speeds decreased by ____ percent.

1.	50%
2.	25%
3.	10%
4.	10% (or 5% of the packages which must comply)
5.	15%
6.	5%

__1__ YES: Line speeds increased by 10% percent

9. What labor changes were or will be necessary due to this tamper-resistant regulation? (PLEASE CHECK AND COMPLETE)

__5__ No change

__1__ Decrease - Total cost $ 60,000 Amortized over 3,500,000 packages

__7__ Increase - Total cost $_____ Amortized over _____ packages

1.	$ 80,000	1,500,000
2.	unknown	unknown
3.	unknown	unknown
4.	200,000	60,000,000
5.	16,000	250,000
6.	60,000	30,000.000
7.	unknown	unknown

10. Did or will you experience additional costs for graphics/artwork in order to produce complying tamper-resistant packages? (CHECK)

14 YES 0 NO

If YES: Please indicate which product required the graphics change and the cost per package.

	PRODUCT	COST PER PACKAGE
1.	Cough syrup, cold tablets	No significance
2.	Rectal ointment and suppositories	Not answered
	Nasal solutions	--
	Nasal spray	--
3.	Vitamin drops	$ 100
	Vitamin tablets	100
4.	Capsules, tablets, powders	Not answered
	Liquid products	--
	Creams, ointments	--
	Suppositories	--
5.	Mouthwash; cough and cold liquid products; tablets and capsules; lozenges	Not answered
6.	All products	Unknown
7.	Hay fever inhibitor; motion sickness inhibitor; diarrhea reliever	$500 one time cost
8.	Cough/cold tablets, capsules, and liquids	$ 200
	Analgesics	$ 200
	Diet products	$ 200
9.	Aspirin (3 products)	$ 500
	O-T-C liquids (6 products)	$ 500
	O-T-C (labeled as foods)(20 products)	$ 500
10.	Antacids - liquids and tablets	$ .0003
	Vitamins	.00225
	Laxatives - capsules and bulk powder	.00225
	Various tablets	.00225
11.	O-T-C antacid liquid and tablets; mouth irritant drops; ear wax control drops	Cost of scrap to meet 5/83 deadline
12.	Liquid cough preparations; O-T-C solid forms - capsules and tablets in bottles and blisters	One time mechanical change
13.	All O-T-C products	Not answered
14.	Laxative tablets, powder, and liquids; cough preparations - liquid; cold medicine - capsules and tablets	Minimal

11. What was the main factor in determining which tamper-resistant system(s) your company chose? (CHECK ONE)

A) 2 Most effective option
B) 1 Lowest cost option
C) 3 Most readily available materials/system (time)
D) 3 Most compatible with existing packaging
E) 0 Most compatible with existing machinery system
F) 4 Other (specify)

- D and E (1)
- A, B, C, D, E (2)
- FDA Guidelines (1)

12. If you have changed your advertising because of this regulation, please indicate how much you expect this to cost you for the first year. (CHECK ONE AND COMPLETE)

13 No Change
0 Decrease - Total Cost $ _____ Amortized over ____ packages
0 Increase - Total Cost $ _____ Amortized over ____ packages

13. The new regulation requires that all affected products sold at the retail level on or after February 6, 1984, be in tamper-resistant containers. If your company still has non-tamper-resistant containers on the retail shelves at that time, what do you plan to do with the non-complying product? (CHECK ONE AND INDICATE EXPECTED LOSSES)

13 Expect most non-complying packages to be sold by that time.
0 Plan to recall and repackage product in tamper-resistant packages
0 Plan to recall and discard product
0 Plan to have retailers dispose of product and give them credit for lost product.
0 Other plans for non-complying packages (Please specify)

EXPECTED LOSSES:

Cost of repackaging	$ 11,600	(NOTE: Answered by only one company)
Number of packages refilled	200,000	
Transportation Costs	$	
Product loss in dollars	$	
Number of packages lost		
Other expected losses		

14. How did or how do you expect this regulation to affect your company's sales volume for this first year beginning with the issue date (November 5, 1982) of the tamper-resistant regulation? (CHECK ONE AND COMPLETE)

12	No change		
0	Decrease - Dollar value $ _____	Number of packages	_____
2	Increase - Dollar value $ _____	Number of packages	_____

1.	1.3	1
2.	not specified	not specified

15. Do you expect your additional costs caused by this regulation to affect the retail price of the product?

4 YES: increased cost per package $ _____

1.	$ .15
2.	--
3.	.05
4.	--

_____ NO: cost per package we will absorb $ _____

1.	--
2.	--
3.	--
4.	--
5.	2 - 3 cents
6.	--
7.	--

16. Please note any additional costs or changes due to this tamper-resistant regulation which we may have overlooked.

NOTE: Not answered

17. COMMENTS:

NOTE: No further comments

APPENDIX K

DATA - SUPPLIER COMPANIES

APPENDIX K

DATA - SUPPLIER COMPANIES*

SECTION 1: GENERAL INFORMATION

1. Your area of responsibility: (CHECK ONE)

3	Packaging	0	Quality Control
24	Sales/Marketing	2	Production/Manufacturing
0	Purchasing	0	Project Engineering
9	Corporate Management	0	R&D
1	Regulatory Affairs	1	Other (Please specify) Owner of Company

2. Nature of Company: (CHECK ONE)

11	Machinery Supplier	0	Drug Manufacturer
7	Materials supplier	0	Food Manufacturer
13	Closure Supplier	2	Container Supplier
7	Other (Please specify):		

- Label supplier (2)
- Machinery/Container/Closure Supplier (1)
- Machinery/Material Supplier (2)
- Machinery/Closure Supplier (2)

3. Is your company: (CHECK ONE)

1	Local	10	National
3	Regional	26	International

4. Annual sales for your divisions involved in tamper-resistant packaging (last fiscal year).

5	Unknown	4	$100 million to $250 million
15	$0 to $5 million		$250 million to $500 million
2	$5 million to $10 million		$500 million to $750 million
10	$10 million to $50 million		$750 million to $1 billion
2	$50 million to $100 million		$1 billion and up

*40 usable surveys were returned. Many surveys were not completely filled out.

5. What materials or devices do you supply that are now being used to make tamper-resistant packages? (PLEASE CHECK)

5	none (if you supply equipment go to Question #6)		
6	film wrappers	10	bottle seals
1	blister or strip packs	3	tape seals
0	bubble packs	8	breakable caps
10	shrink seals or bands	3	sealed tubes
0	sealed cartons	0	aerosol containers
2	adhesive		
2	foil, paper or plastic pouches		
13	other (please specify)		

-closures with tamper-resistant innerseals (1)
-overseals that are crimped on (1)
-custom injection molding (2)
-heat or pressure sensitive liners (1)
-foam cores (cones?) (1)
-labels (3)
-printing ink (2)
-tamper button - vacuum (1)
-aluminum alloy clips for film bags (1)

NOTE: Some companies supplied two or more tamper-resistant materials or devices.

6. What machines do you supply that are now being used to produce tamper-resistant packages?

11	None	3	Cappers
5	Band applicators	0	Tube formers
13	Shrink tunnels	0	Blister/bubble formers
6	Shrink wrappers	2	Pouch formers
2	Cartoners	0	Tape applicators
1	Adhesive attachments for cartoners	0	Induction sealers
9	Other (please specify)		

-equipment to manufacture caps (1)
-injection molding machinery - especially adapted for tamper-resistant closures (1)
-tooling to crimp seals (1)
-label applicators (3)
-impulse, heat, vacuum sealers (1)
-conduction sealers (1)
-core (cone?) applicators (1)

NOTE: Some supplied two or more machines used to produce tamper-resistant packages.

7. Did or will you increase production capacity to meet the demand for your tamper-resistant materials, devices, or forming/application equipment? (PLEASE CHECK)

__22__ YES __17__ NO

If yes: Did you increase capacity by purchasing new machinery/equipment? (PLEASE LIST EQUIPMENT, NUMBER PURCHASED AND COST)

__11__ Check here if none was purchased.

MACHINE	NUMBER PURCHASED	COST EACH
1. Tooling	10	$ 750
2. Printing and cutting equipment	2	$ 35,000
3. Lining machinery	3	$ 90,000
Hot stamp	3	70,000
Printer	3	92,000
Injection molding	14	155,000
4. Tools	4	$250,000 (total)
5. Injection molding equipment	10	$150,000
6. Complete manufacturing line	1	$475,000

8. What labor changes were or will be necessary at your company due to this tamper-resistant regulation? (PLEASE CHECK)

__27__ No change

__0__ Decrease in labors hours-Total Savings $_____

__11__ Increase in labor hours-Total Cost $25,000 (only one company answered)

9. What changes have you had or do you expect to have in Advertising costs? (From November 5, 1982 to November 6, 1983) CHECK ONE AND COMPLETE

__20__ No change

__1__ Decrease-Total Cost $_____

__18__ Increase-Total Cost $_____

-$18,000
-$10,000
-$20,000
-$10,000
- 50 percent
-$10,000-$15,000
-$20,000
-$50,000
- 50 percent
-$25,000
-$50,000
-$ 5,000
-$30,000

10. How did or how do you expect this regulation to effect your company's sales volume? (CHECK ONE AND COMPLETE)

14 No change in sales volume expected

0 Decreased volume: Dollar value $____

25 Increased volume: Dollar value $____

-$1,000,000	-$3,000,000
-$ 185,000	-$ 250,000
-$ 500,000	-$4,000,000 to $5,000,000
-$ 100,000	-$ 100,000
-$1,000,000	-$5,000,000 to $10,000,000
-$5,000,000	-$3,000,000

11. Do you expect your additional costs caused by this regulation to be passed on to your customers?

25 We did not incur additional costs due to this regulation.

11 YES we will pass costs to our customers

____ NO we will absorb additional cost

12. Please not any additional costs or changes due to this tamper-resistant regulation which we may have overlooked.

NOTE: Not answered

13. COMMENTS PLEASE

NOTE: No further comments

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