HB

247

COMMITTEE REPORT

SENATE

FURTHER:

Date: _____

Mr. President:

The Committee on _____ has had _____

under consideration and (a majority of the committee) (the committee) reports it back with the following recommendations:

[ ] do pass [ ] do not pass

[ ] do pass with attached amendments(s)

[ ] replace with CS for _____ [ ] same title [ ] new title

and recommends _____

[ ] AND attaches a "Letter of Intent" [ ] New Fiscal Note

[ ] reports it back without recommendation

[ ] referred to the _____ Committee

MEMBERS SIGNING
DO PASS

_____

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MEMBERS HAVING
OTHER RECOMMENDATIONS:

_____

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_____

CHAIRMAN

FILE W1114 CSHB 247

Alaska State Legislature

SENATOR
ROBERT H. ZIEGLER, SR.
307 BAWDEN STREET
KETCHIKAN, ALASKA 99901

While in Juneau
POUCH V
JUNEAU, ALASKA 99811

Senate

VICE CHAIRMAN
SENATE RESOURCES COMMITTEE

MEMBER
SENATE JUDICIARY COMMITTEE

WESTERN STATES LEGISLATIVE
FORESTRY TASK FORCE

WESTERN CONFERENCE COUNCIL
OF STATE GOVERNMENTS

May 5, 1983

Senator Bill Ray,
Chairman
Senate Judiciary Committee
Alaska State Legislature
Juneau, Alaska

Re: CSHB 247

Dear Bill:

This act relates to tampering with an item that is a food, drug, or cosmetic, and delivering, dispensing or distributing those items.

Section 1(a) deals with criminal mischief in the first degree and enumerates all those bad things you can do with intent to cause physical injury to another person. No doubt such legislation was prompted by the Tylenol episode in Chicago.

Section 2 of the bill contains several definitions. It occurs to me, and you might check this out with John G., that perhaps we should amend the bill to include a definition of "tamper".

I'd recommend passage.

Regards,

R. H. Ziegler, Sr.

Robert H. Ziegler, Sr.

RHZ:lk

HB 244

AS11.46.490 DOCUMENT= 1 OF 1 PAGE = 1 OF 2
CHAPTER = 11.46
SECTION = 11.46.490
TITLE = 11
HEADINGS TITLE 11.
Criminal Law.
CHAPTER 46.
Offenses Against Property.
ARTICLE 3.
Arson, Criminal Mischief, and Related Offenses.
CITATION Sec. 11.46.490.
CATCH LINE
DEFINITIONS.
TEXT AS used in secs. 400 - 490 of this chapter, unless the context requires otherwise,

(1) "oil or gas pipeline or supporting facilities" means real property or tangible personal property used in the exploration for, production or refining of, or pipeline transportation of oil, gas, or gas liquids, except for property used solely in the retail distribution of oil or gas;

(2) "tamper" means to interfere with something improperly, meddle with it, or make unwarranted alterations to its existing condition;

(3) "utility" means an enterprise, whether publicly or privately owned or operated, which provides gas, electric, steam, water, sewer, or communications service, and any common carrier;

(4) "widely dangerous means" means any difficult-to-confine substance, force, or other means capable of causing widespread damage, including fire, explosion, avalanche, poison, radioactive material, bacteria, collapse of a building, or flood.

HISTORY (Sec. 4 ch 166 SLA 1978)

See pg 2

STATEMENT BY

ARTHUR HULL HAYES, JR., M.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

—

OCTOBER 15, 1982

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

I am here today to discuss with you the events surrounding the recent contamination of Extra-Strength Tylenol capsules and to share with you our thoughts and concerns regarding this tragic event. On behalf of Secretary of Health and Human Services Richard Schweiker and myself, I would like to acknowledge the excellent cooperation we have received from industry, State and local authorities, and the Federal Bureau of Investigation who have responded swiftly and effectively to this emergency.

Based on the September 30, 1982 report of deaths in Chicago by a Cook County medical examiner, the manufacturer of Tylenol, McNeil Consumer Products Co. of Fort Washington, Pennsylvania immediately removed the lot from the marketplace nationwide which had been linked to the deaths. On October 1, the manufacturer removed a second lot from the marketplace nationwide which had been linked to an additional death. In the greater Chicago area, all Extra-Strength Tylenol capsules were withdrawn.

At the same time, the Food and Drug Administration (FDA) issued press releases on September 30 and October 1 (a press conference was also held on October 1) advising consumers not to use Extra-Strength Tylenol capsules until circumstances surrounding the deaths could be clarified. Additionally, FDA began sampling Extra-Strength Tylenol nationally on October 1. Sampling in the Chicago area had begun immediately upon learning of the Tylenol-related deaths on September 30.

FIELD ACTIONS

During the next four days, over a million and a half Tylenol capsules were sampled and tested. Over 1,100 FDA field personnel were committed to collecting and analyzing samples of Tylenol capsules and immediately investigating all reports of deaths or illnesses which might have been associated with the use of Tylenol. Samples were collected in practically all of the States and forwarded to our district laboratories for analysis. I would like to make special mention of the enormous task our analysts faced. Each individual capsule was physically examined and its ingredients chemically analyzed. It was truly an extraordinary effort.

In one instance, our field efforts may have, indeed, prevented an additional death. One bottle taken from the shelves by FDA in the Chicago area proved to be contaminated with cyanide. This was the only bottle containing cyanide that was not associated with a death. None of the capsules outside the Chicago area showed cyanide contamination.

In addition, both plants where the lots involved had been produced were inspected to insure that the contaminant had not been introduced into the product during the manufacturing process. The Philadelphia District Office began inspecting the Fort Washington, Pennsylvania plant on September 30 and the Houston District Office inspected the Round Rock, Texas plant on October 1. We concluded that the contamination was the result of tampering after the capsules had been

shipped to distribution points and, most likely, after they reached the retail shelves. Some of the reasons were:

-- The only cases of injury and death associated with cyanide-contaminated capsules were in the Chicago area and had all occurred within three days--September 29 to October 1.

-- The control numbers directly associated with the injuries and deaths were produced in two widely separated plants at three different times: Fort Washington, Pennsylvania and Round Rock, Texas in January, March, and April 1982.

-- There was no uniformity in the amount of cyanide present in the capsules that were analyzed.

-- FDA laboratory testing of capsules containing cyanide revealed that the gelatin capsule begins to deteriorate 6 to 7 days after being in contact with the cyanide, and samples of capsules collected and analyzed by FDA from a Schaumberg, Illinois drug store and FDA analysis of capsules from victims' bottles revealed beginning stages of such deterioration.

-- The first two control numbers implicated were both shipped to the Chicago area in mid-August 1982. The third lot was first shipped to distribution points in Pennsylvania in May 1982. Subsequent shipments of code 1801 MA were after that date and therefore all were available for adulteration in Chicago at about the same time.

-- The bottle of capsules implicated in one death contained both Regular Strength and Extra-Strength capsules. Only the Extra-Strength capsules contained cyanide. Inspection of the plants revealed distinctly separate processes for the manufacture of the two kinds of capsules and these processes are physically separated one from the other.

-- Local law enforcement agencies have announced that they believe at this time that the tampering took place after the product left the manufacturing plant.

By October 4, FDA also had checked reports of more than twelve deaths or illnesses in areas other than Chicago and none proved to be related to Tylenol. On that same date FDA issued another press release to provide this updated information and to continue to advise against the use of nonprescription Tylenol capsules. Also, from the day the deaths were first reported, my colleagues and I utilized national TV and radio news programs, press conferences and other available means of communication to convey this message to the public.

As authorities continued to investigate the cyanide poisoning deaths in the Chicago area, a report of a Tylenol-related illness involving an Oroville, California man was received by FDA late on Monday evening, October 4. Field investigators were immediately assigned to the area to investigate the incident and acquire samples. Although the man recovered, subsequent analysis of the Extra-Strenth Tylenol capsules from the bottle he had used revealed the presence of strychnine. At this time, although all contaminated Tylenol products were Extra-Strength Tylenol, retailers were notified nationwide on October 5 by the manufacturer to withdraw both Extra- and Regular Strength Tylenol capsules from their shelves. FDA also issued another press release on that date summarizing McNeil's announcement regarding the Oroville situation and restating its warning to consumers to avoid Extra-Strength and Regular nonprescription Tylenol capsules nationwide.

As of today, over 150 reports of deaths or illnesses that might have been related to the use of Tylenol capsules have been received by FDA from across the country. We have investigated each of these reports and have been unable to prove that any subsequent cases have been linked to the taking of contaminated Tylenol. We are continuing to monitor and follow up on additional reports we receive.

HEADQUARTERS ACTIONS

In addition to the efforts undertaken in the field and because of the continuing serious emergency involving the tampering with nonprescription drug products, I utilized our existing emergency procedures for headquarters personnel and 24-hour coverage was provided by the staff. I also created a formal emergency Task Force devoted to the Tylenol problem. The group met at least twice daily to review, discuss and direct the activities of headquarters and field personnel.

These events have, quite understandably, generated concern about package integrity and product security. After discussion with the Secretary, I conferred with The Proprietary Association, a trade association which represents a large number of nonprescription drug manufacturers, on October 3 suggesting that they organize an industry task force to address this problem. They agreed to do so and immediately established the Joint Committee on Product Security. I met with the Committee on October 5 to explore measures to improve product packaging in order to discourage tampering.

Further, a special Expert Technical Committee was appointed to develop standards for tamper-resistant packaging. This group met on

October 7 and 11 and reviewed technologies available to deal with this problem, and a number of packaging types were identified as tamper resistant by a definition developed by the group. An integral part of these discussions has been the availability of necessary packaging that are agreed upon. In addition, individual drug companies have been examining their own packaging to determine what can be done to develop and implement additional tamper-resistant procedures. As you know, the Board of Directors of The Proprietary Association met yesterday and received the report from the Expert Technical Committee. I am advised that Mr. Cope will discuss the substance of that report in his testimony.

There is a need for a Federal standard to implement the packaging requirement. Such requirements and their technical feasibility are the subject of discussion within FDA and The Proprietary Association.

Of concern to us has been the development of State and local laws or proposals to require some form of tamper-resistant packaging. These laws or proposals are an understandable response in the face of this tragic situation. It is important, however, that there not be conflicting laws affecting nationally distributed products in such a way that it is impracticable to market such products. Therefore on October 5, Secretary Schweiker requested FDA to immediately begin drafting a regulation that would require some kind of tamper-resistant packaging for nonprescription drugs. The Secretary stressed the need for uniform consistent standards that adequately protect the public while assuring the availability of nonprescription drug products nationwide.

FDA currently possesses the legal authority to promulgate regulations governing the design of containers to discourage or indicate the occurrence of tampering. Specifically, section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. sec. 351(a)(2)(B)] authorizes FDA to issue good manufacturing practice regulations (GMPs) for drug products.

GMPs are those measures that manufacturers take to assure that their drug products are of adequate quality, including measures to assure that products remain of adequate quality throughout the chain of distribution. This GMP authority has been used to require drug containers to guard against foreseeable external factors that could cause product deterioration or contamination. These regulations were not intended to cover tampering. Tampering has been uncommon and sporadic, and has therefore not been considered, until now, to be the type of threat to product integrity for which an industry-wide response is necessary. But, in the light of the recent events in Chicago and Oroville, it is clear that good manufacturing practices should now include the use of tamper-resistant packaging to discourage or indicate the occurrence of tampering. Such packaging is necessary to assure that over-the-counter (OTC) drug products meet federal requirements for safety, quality, and purity at the time of purchase by the ultimate consumer.

It must be recognized that the initiatives described above will not happen overnight. Although we expect to publish the regulation in the near future, it is going to take time for industry to get the equipment in place in the plants and to begin marketing these products. It

should also be emphasized that a tamper-proof package is not possible. However, we believe that we can improve upon the packaging for these products using existing and developing technologies by making them more resistant to tampering of any sort. At the same time, we must help to educate consumers to be alert to signs that indicate tampering. Our goal in these efforts is to reduce the risk of injuries or deaths to consumers now and in the future. I want to assure you that Secretary Schweiker and I give this matter the highest priority.

CONSUMER INITIATIVES

Initiatives are underway by health professionals, the industry and FDA to develop ways in which we can best inform and educate the public about how critical it is for all of us to be as observant as possible with regard to the condition of the products we buy. We will be building upon our existing programs through cooperation with the private sector to develop ways to disseminate information and to impress upon consumers that they have a personal responsibility to heighten their sense of awareness in this area. In fact, the National Council on Patient Information and Education plans to form a group which will deal with various aspects on patient and consumer responsibility. We are working closely with the Council. The Council, headed by former Congressman Paul Rogers, held its first meeting on October 12, 1982.

INTERNATIONAL COMMUNICATIONS

We also undertook to disseminate information to the international community.

On Friday, October 1, the text of Dr. Novitch's statement at the noon press conference was sent by telegram to the World Health Organization (WHO) offices in Geneva, Copenhagen, and Washington. An all-post telex was sent Friday evening by the Department of State. That evening, a telex explaining events up to that time was also sent to 64 government drug regulatory authorities and WHO.

Over the next two days, we continued to provide WHO and the State Department with additional information as it became available and requested that the various health ministries be provided with this updated information. Another telex was sent to international drug regulatory authorities.

Further, on October 8, we again contacted the State Department updating domestic information on the Tylenol situation, listing the 11 foreign countries in which Tylenol capsule products are manufactured and/or marketed, and providing information on the Johnson and Johnson preferred method of disposing of bottled Tylenol capsules. We provided a list of the 11 foreign affiliates of Johnson and Johnson and explained that these affiliates had already established communications with the local health ministries regarding sales of Extra-Strength Tylenol capsules. We transmitted this same information to WHO Headquarters, WHO regional offices, and the European Economic Community. This information was also transmitted to international drug regulatory authorities.

The willful contamination of products intended to benefit consumers is repulsive to us all. I can assure you that the Secretary and I are personally committed to moving quickly to provide additional safeguards to help protect the public.

Thank you Mr. Chairman. This concludes my prepared testimony. I will be happy to answer any questions you may have.

Federal Register

Friday
November 5, 1982

Part IV

Department of Health and Human Services

Food and Drug Administration

Tamper-Resistant Packaging Requirements; Certain Over-the-Counter Human Drugs and Cosmetic Products; Contact Lens Solutions and Tablets; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 211, 314, and 700

[Docket No. 82N-0330]

Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing requirements for tamper-resistant packaging for all over-the-counter (OTC) human drug products, except dermatologics, dentifrices, and insulin, and for cosmetic liquid oral hygiene products and vaginal products. These regulations will also require a statement on the labeling of such products to alert consumers to the specific tamper-resistant feature of the package. This action is taken to assure package integrity and product security in light of the recent cases of malicious adulteration of OTC drug products that resulted in seven deaths in the Chicago area and other cases in several geographic areas nationwide.

DATES: Packaging requirements are initially effective February 7, 1983 for all OTC drug products subject to this rule (except oral and vaginal tablets and vaginal and rectal suppositories) and for cosmetic liquid oral hygiene products and liquid vaginal products packaged on or after that date. Labeling requirements for all products and packaging requirements for oral and vaginal tablets and vaginal and rectal suppositories are effective on May 5, 1983. Products packaged prior to May 5, 1983 and held for sale at the retail level must be in compliance with the tamper-resistant packaging requirement, but not the distinctive indicator or barrier to entry or labeling requirements of the regulations by February 6, 1984. Comments by December 6, 1982. For further details see the effective dates information following the text of the regulations.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For drugs: Eileen R. Hoolkinson, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3490.

For cosmetics: Heinz J. Eiermann, Bureau of Foods (HFF-440), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1500.

SUPPLEMENTARY INFORMATION: FDA is issuing final regulations to require tamper-resistant packaging for certain over-the-counter (OTC) drug and cosmetic products. OTC drug products subject to these regulations include all OTC drug products except dermatologics (i.e., products applied to the skin), dentifrices, and insulin. The OTC drug products that are covered by these regulations include oral (except dentifrices), nasal, otic, ophthalmic, rectal, and vaginal drug products. Cosmetic products covered by these regulations are liquids that are used orally, such as mouthwashes, gargles, breath fresheners, etc., and vaginal cosmetic products. The agency is requiring that the packaging of these products be capable of providing consumers with visible evidence of package tampering. In response to seven recent deaths linked to Extra-Strength Tylenol capsules found to be contaminated with cyanide and to other recent tampering incidents nationwide, this action is being taken to provide safeguards against the future occurrence of such incidents. Further, the agency is requiring a labeling statement on the container to alert the consumer to the specific tamper-resistant feature. In addition, ophthalmic device adjuncts such as contact lens solutions and lubricants are covered by a separate final regulation published elsewhere in this issue of the Federal Register.

I. Background

The Chicago Poisonings

On September 30, 1982, FDA was advised that several persons living in the Chicago metropolitan area had died from cyanide poisoning after taking Extra-Strength Tylenol capsules. Capsules taken from bottles of Extra-Strength Tylenol in the possession of the victims were chemically analyzed by local authorities, and some of the capsules in these bottles were found to contain lethal amounts of potassium cyanide. By October 1, several more Chicago area residents had died from cyanide poisoning after ingesting Tylenol Extra-Strength capsules, bringing the total of deaths to seven.

On September 30, government authorities and the manufacturer of Tylenol, McNeil Consumer Products, Fort Washington, PA, began an investigation to determine the manner in which the capsules had become contaminated with cyanide. The capsules involved in the seven deaths were manufactured in two plants, one in Pennsylvania and one in Texas. FDA investigators immediately inspected both plants. Based on the plant inspections, FDA concluded that the contamination had not occurred at either plant, but rather was the result of tampering after the capsules had been shipped to distribution points and, most likely, after they had reached the retail shelves. Further evidence to support this position is described below.

The pattern of contamination revealed during subsequent events was inconsistent with the theory that the cyanide had been introduced either at the source of manufacture or at intermediate points in the chain of distribution. The capsules involved in the Chicago deaths were manufactured at three different times and in two widely separate plants, yet they were apparently purchased within a short period of time in one geographic area. FDA and other agencies have tested 1.7 million Tylenol capsules and investigated about 270 incidents in which death or illness was thought possibly to be connected with the use of Tylenol. To date, no Tylenol capsules outside the Chicago area have been found to contain cyanide, and there has been no other confirmed case in which cyanide poisoning was linked to the ingestion of Tylenol. That the poisoning deaths occurred in only one location during a brief space of time, although the capsules were made in two places at different times, makes it extremely unlikely that the cyanide contamination occurred before the capsules arrived in the Chicago area.

In addition, certain other facts strongly support the position that the tampering occurred after the capsules had been shipped to distribution points and, most likely, after they reached the retail shelves. One of the bottles associated with a death held both Extra-Strength and Regular Strength capsules; only the Extra-Strength capsules contained cyanide. Some of the contaminated capsules showed visible signs of tampering. FDA laboratory testing of capsules containing cyanide revealed that the gelatin capsule begins to deteriorate 6 to 7 days after first exposure to cyanide; samples of capsules collected and analyzed by FDA from a drug store in Schaumberg, IL, and from victims' bottles revealed the beginning stages of such deterioration.

Although conclusive evidence of the exact circumstances of the tampering does not exist, it is believed that one or more persons obtained the Extra-

Strength Tylenol capsules, contaminated them with cyanide, inserted these capsules into the bottles, returned them to the boxes in which they are sold, and surreptitiously placed the boxes on the shelves of the stores from which the victims purchased them. These Extra-Strength Tylenol capsules were packaged in plastic snap-top bottles, with cotton wadding inserted into the neck of the bottle. The bottles were placed inside individual cardboard cartons. Although packaged in compliance with current FDA requirements, neither the bottles nor the cartons were sealed or otherwise fabricated to ensure that access to the product required the destruction or visible disturbance of the package.

Response to the Chicago deaths

The tragic events in Chicago elicited response on several levels. Authorities in Illinois, aided by Federal Government agencies, launched an intensive investigation to identify the person or persons who contaminated the Tylenol. Municipal authorities in the Chicago area took immediate steps to protect their citizens against further poisonings by cautioning against the use of Tylenol capsules and, in the city of Chicago, banning the sale and use of all Tylenol products. FDA conducted a nationwide campaign to sample and analyze Tylenol capsules and other Tylenol products susceptible to contamination, and warned against the use of Extra-Strength and Regular Strength Tylenol capsules. McNeil withdrew Extra-Strength, and then Regular Strength, Tylenol capsules from sale and warned against the use of all Tylenol capsules. State and local jurisdictions throughout the country took a variety of precautionary measures. Police and regulatory authorities investigated dozens of reports of possible related incidents. Poison control centers around the country responded to questions from concerned consumers.

In addition to these actions aimed at the immediate problem, several jurisdictions are considering enacting laws to improve the security of drug product packaging to deter tampering or alert the consumer to its occurrence. Cook County, IL, approved an ordinance on October 4, 1982, requiring all OTC drugs to be sold only in sealed containers. On October 6, the city of Chicago submitted a similar ordinance to the city council.

On the national level, Secretary of Health and Human Services Richard Schweiker requested FDA to begin drafting a regulation to require tamper-resistant packaging for OTC drugs. Several Members of Congress stated their intention to introduce appropriate legislation, and on October 15, the House Subcommittee on Health and the Environment conducted a hearing to explore the packaging security issue.

At the request of FDA, the Proprietary Association, a national trade association representing manufacturers of OTC drugs, announced the formation of a Joint Committee on Product Security to explore ways of reducing the risk of malicious tampering with OTC drugs. A special Expert Technical Committee of industry experts, established to develop specific recommendations for tamper-resistant packaging, met in Washington, DC, and reported its conclusions on October 14, 1982, to the Board of Directors of the Proprietary Association in New York. On October 20, the Board formally transmitted recommendations for action to FDA.

Other Poisonings.

Since the Tylenol poisonings, several cases of serious injuries have been reported resulting from the use of products that have been tampered with. These incidents, although not the initial impetus for these regulations, further demonstrate the need for their prompt implementation.

Need for Federal Regulation To Improve OTC Packaging Security

The poisoning fatalities make plain the gravity of the risk to which the nation's population is exposed from malicious tampering with drug products sold over-the-counter to the consumer. The Tylenol incident occurred in the Chicago area, but is was followed by others elsewhere in the country. Nor is the potential for such tampering confined to one manufacturer's products. Incidents of OTC drug product tampering involving products other than Tylenol have occurred in recent weeks. The combined incidents demonstrate that the need for adequate product security is national in scope and requires an industrywide response.

FDA is the agency designated by Congress to assure the safety of drugs marketed in the United States. It is, therefore, appropriate for FDA, in accordance with Secretary Schweiker's request, to develop and issue regulations to meet the problem of OTC product tampering on a national basis. A Federal requirement will not only help to protect the entire population, it will also obviate the need for State and local laws aimed at accomplishing the same objective for smaller numbers of people. OTC drugs are an important component of the nation's health care system. Conflicting packaging security requirements imposed at the local level would create a strong likelihood that distribution of OTC drugs might be disrupted, thus limiting the available supply of OTC drugs. In addition, unnecessary costs might be imposed on purchasers of OTC drugs as a result of the efforts by manufacturers and distributors to meet differing standards.

An FDA tamper-resistant packaging regulation applicable uniformly to all manufacturers of OTC drug products in all geographic markets will provide the public health protection the country needs and deserves, without unduly burdening the national system of drug distribution and without raising health costs more than necessary to achieve the intended result.

FDA is also responsible for assuring the safety of cosmetic products. Most cosmetic products are applied topically to the skin. Such topical products do not pose the same health threat if tampered with as do products that are ingested, inserted, inhaled, or intended for ophthalmic use. For this reason, neither dermatologic OTC drugs, nor topically applied cosmetics, are subject to the regulations issued in this document.

Because some cosmetics such as liquid cosmetic mouthwashes are used within the oral cavity, they come in contact with sensitive mucous membranes and small but significant amounts are usually ingested. The agency believes, therefore, that these products present the same high degree of risk from tampering that is presented by the drugs covered by this final rule. The agency is aware of a recent incident in which a cosmetic mouthwash was contaminated with acid by a person who tampered with the product before retail sale. Accordingly, FDA is requiring that liquid cosmetics used orally be marketed in tamper-resistant packaging meeting the criteria of this final rule.

Vaginal drug and cosmetic products, most of which are liquid in form, are also highly susceptible to tampering and are capable of causing serious injury if tampered with. Thus, these products are also included in this final rule.

Many OTC drug and cosmetic products are already packaged in tamper-resistant containers that are sealed so that the contents cannot be used without obvious destruction of the packaging seal. (FDA notes, however, that such packaging, without an accompanying label statement, may not be completely effective, as evidenced by several recent incidents involving ophthalmic products.) The agency recognizes that although the technology is currently available to make all packaging of the products mentioned

above tamper-resistant. It will take manufacturers some time to adapt the technology to their particular products. The agency concludes, however, that such packaging is in the interest of the public health and should be required as soon as possible. This final rule will make available to consumers more secure packaged OTC drug and cosmetic products, while allowing manufacturers and packers flexibility by taking into account the availability of the necessary packaging materials and machinery for manufacturers to use, and the time needed to set into place any new requirements. The agency encourages drug and cosmetic manufacturers to make the necessary packaging and labeling changes, if possible, before the effective dates imposed by this final rule and it anticipates that a large segment of the industry will comply fully before the various effective dates discussed later in this document.

II. Concept of Tamper-Resistance

The Proprietary Association/FDA Expert Technical Committee on Tamper-Resistant Packaging met on October 7 and 21 to consider measures that would ensure container integrity and make tampering evident if it occurred. On October 14, the Committee's conclusions were considered by the Board of Directors of the Proprietary Association. On the same day, the Board recommended that FDA adopt a regulation requiring OTC drug packaging to meet a tamper-resistance performance standard. The standard would require OTC drug packages to have an indicator or barrier to entry that would provide the consumer with visible evidence that the package had been tampered with or opened. The Proprietary Association also recommended that packages bear a label statement describing the tamper-resistant mechanism.

Based on the information developed by the Expert Technical Committee, on the Proprietary Association's recommendation, and on the agency's own knowledge and experience, FDA has concluded that adequate public health protection against malicious tampering will be provided by the use of tamper-resistant packaging meeting the criteria discussed below.

The agency defines a tamper-resistant package as 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. Tamper-resistant packaging may involve immediate-container/closure systems or secondary-container/carton systems or any combination thereof intended to provide a visual indication of package integrity when handled in a reasonable manner during manufacture, distribution, and retail display. The visual indication is required to be accompanied by appropriate illustrations or precautionary statements to describe the safeguarding mechanism to the consumer. To reduce the possibility that the security mechanism can be restored after tampering, the agency is also requiring that either the tamper-resistant feature be designed from materials that are generally not readily available (e.g., an aerosol system) or that barriers made from readily obtainable material (e.g., plain tape, paper seals, clear plastic) carry a distinctive design or logo.

The agency stresses that tamper-*proof* packaging is not possible. Although the requirements in this final rule will reduce the potential for tampering, they cannot eliminate it. Neither the agency nor manufacturers can guarantee protection against malicious tampering but can only make tampering more difficult by making product packaging more *resistant* to tampering. For this reason, the agency will consider any labeling statement suggesting that the package is tamper-proof, as contrasted with tamper-resistant, to be false and misleading. Consumers must act to protect themselves from injury by inspecting the condition of the packages they buy, the tablets and capsules they take, and the liquids they drink.

The standards for tamper-resistant packaging established by this final rule will allow manufacturers flexibility in determining which packaging system to use. Several packaging options are available to provide increased assurance of tamper-resistance for a large number of products. Alternative systems that provide comparable margins of assurance will also be acceptable under this final rule because the agency realizes that the state of the art of this technology is evolving. FDA considers the packaging systems listed below, which are currently available, to be examples of those capable of meeting the tamper-resistant requirement of this final rule. It is not the agency's intent to preclude technological innovation that may introduce totally different systems for providing protection to the consumer against tampered products.

1. *Film wrappers.* A transparent film with distinctive design is wrapped securely around a product or product container. The film must be cut or torn to open the container and remove the product.

2. *Blister or strip packs.* Dosage units [illegible] are sealed in clear plastic or [illegible] individual compartments must be torn or broken to obtain the product [illegible]. The product and [illegible] are sealed in plastic and [illegible] on a display card. The [illegible] must be torn or broken to remove the product.

3. *Bands, shrink neck bands, flanges or wrappers* with distinctive design [illegible] heat or drying to secure [illegible] of the cap and container. The seal must be cut or torn to open the container and remove the product.

5. *Foil, paper, or plastic pouches.* The product is enclosed in an individual pouch that must be torn or broken to obtain the product.

6. *Bottle seals.* Paper or foil with a distinctive design is sealed to the mouth of a container under the cap. The seal must be torn or broken to open the container and remove the product.

7. *Tube seals.* Paper or foil with a distinctive design is sealed over all carton flaps or a bottle cap. The seal must be torn or broken to open the container and remove the product.

8. *Breakable caps.* The container is sealed by a plastic or metal cap that either breaks away completely when removed from the container or leaves part of the cap attached to the container. The cap must be broken to open the container and remove the product.

9. *Sealed tubes.* The mouth of a tube is sealed and the seal must be punctured to obtain the product.

10. *Sealed carton.* All flaps of a carton are securely sealed and the carton must be visibly damaged when opened to remove the product.

11. *Aerosol containers.* Aerosol containers are inherently tamper resistant.

The agency urges manufacturers and packagers, in designing the tamper-resistant packages, to take into consideration that such packaging should not be so difficult to open that arthritics and others manually impaired cannot open them.

III. Provisions of the Rule

Applicability

FDA is revising its regulations to establish requirements for tamper-resistant packaging for all OTC drug products, except dermatologics, dentifrices, and insulin, and for cosmetic liquid oral hygiene products and vaginal products. FDA's current good manufacturing practice (CGMP) regulations (21 CFR Part 211) are intended to provide assurance that drug

product quality does not fall below that which is feasible and available under contemporary technology. FDA's cosmetic regulations describe circumstances under which cosmetics are adulterated or misbranded, or both.

In addition to establishing a tamper-resistant packaging requirement, the final rule also imposes a requirement that the package label of the products subject to this final rule alert the consumer to the existence of the specific tamper-resistant mechanism. This requirement is needed to assure that the tamper-resistant packaging mechanism achieves its intended purpose. Failure to comply with either requirement will result in the affected product's being considered adulterated under section 501 (a)(2)(B), (b), or (c), or 601 (a) and (c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351 (a)(2)(B), (b), or (c), or 361 (a) and (c)). Failure to comply with the labeling requirement or the addition of labeling suggesting that the packaging is tamper-proof will result in the product's being considered misbranded under section 201(n), 502 (a) or (c), 602 (a) or (c) of the act (21 U.S.C. 321(n), 352 (a) or (c), 362 (a) or (c)). Products that are imported into the United States will be required to meet these requirements as well.

This final rule applies to all nonprescription drug products (other than dermatologics, dentifrices, and insulin), and to cosmetic liquid oral hygiene products and vaginal products. Dermatological OTC drug products (i.e., those applied to the skin), dentifrices, and insulin, and cosmetic products other than liquid oral hygiene products and vaginal products are not covered by this final rule at this time because of the lower probability of tampering or the less severe consequences from tampering with these products than with those products that are ingested, inserted, inhaled, or intended for ophthalmic use.

This final rule requires manufacturers and packers of products subject to this rule to package their products for retail sale in tamper-resistant packages. The agency contends that manufacturers and packers can comply with these regulations through the use of currently available packaging technology, which has been shown to be both feasible and valuable in assuring product quality.

The agency concludes that by specifying a result to be achieved rather than specific kinds of packaging systems for particular products, it is providing manufacturers flexibility to determine for themselves the most cost-effective packaging system that produces a tamper-resistant package for their products. Manufacturers and packers are, of course, free to adopt a packaging technology not listed in this final rule if that technology produces a tamper-resistant package. Conversely, use of one of the identified technologies does not, by itself, constitute compliance with the requirement for the use of a tamper-resistant packaging system if the application of the technology in a particular case does not meet the standard established in this final rule (e.g., if the system is inappropriate to the product or is faulty in design).

In addition to requiring tamper-resistant packaging, this final rule also requires the labeling of the affected products to contain a statement describing the tamper-resistant feature of the package and advising consumers that, if the feature is breached or missing when the product is purchased, tampering may have occurred. Tamper-resistant packaging with an appropriate labeling statement will be more likely to protect consumers because the consumer will be in a better position to detect tampering when he or she has knowledge that a tamper-resistant feature has been incorporated into the package design. For example, ophthalmic products, including both drugs and contact lens solutions (regulated as devices), are now required to be sealed so that the contents cannot be used without destroying the seal (21 CFR 200.50), but a labeling statement drawing the consumer's attention to the seal is not required. The agency is aware of incidents in which products subject to that requirement may have been maliciously adulterated, with subsequent injury to consumers. A label statement describing the purpose of the seal and cautioning against purchase if the seal were broken or missing is now required by this final rule for ophthalmic OTC drug products. In a separate document published elsewhere in this issue of the Federal Register, the agency is establishing a requirement for a statement in the labeling of contact lens solutions to alert consumers to the tamper-resistant features of the package.

Although this final rule applies to many OTC drug products and cosmetics, the agency recognizes that existing packaging or marketing practices for some products or classes of products may provide adequate protection for consumers, but not meet the specific requirements of the regulations. Thus, FDA also is establishing in the regulations a procedure for manufacturers and packers to obtain exemptions from the tamper-resistant packaging requirement, the labeling requirement, or both. Although an exemption may be sought through the citizen petition procedures in § 10.30 (21 CFR 10.30), the agency believes instances justifying an exemption will be rare.

Because of the importance of the public health concerns addressed by these regulations, the agency has established an early effective date for them. The effective date provisions are described more fully below. Some manufacturers may have difficulty in meeting the early effective date of the regulations. The equipment needed to implement tamper-resistant packaging is often built on order and therefore may not be readily obtained in a short period of time. Moreover, these regulations will create additional demand for packaging equipment and, therefore, the supply of certain equipment may not be adequate for many months. If manufacturers cannot obtain necessary equipment in time to comply with the effective date provisions, it may be necessary to stay the effective date for particular products to avoid disruption of the market for these products. Stays under the citizen petition procedures in § 10.30 may be requested for any aspect of the regulations, including those relating to the label statement and the use of a distinctive barrier to entry.

The agency will accept petitions for stays of the effective date, but only if manufacturers and packers adequately demonstrate that they have taken all reasonable steps to apply tamper-resistant packaging technology to their products, but cannot comply by the effective date or cannot get new labeling printed by the effective date. The showing must include a description of the tamper-resistant packaging technology the petitioner proposes to use; a description of the facilities and equipment needed to apply that technology; a timetable identifying the date when the technology was chosen, the date when the facilities and equipment will be available for applying the technology to the product, and the date by which the product will be in compliance with the regulations. A lengthy stay will not be granted if the petitioner has selected a technology that will require a substantial period of time to obtain and apply and the petitioner could, without undue expense, adequately comply with the regulation by using another technology.

To assist the agency in handling any petition for a stay of the effective date or for an exemption for a covered product, it is requested that the submission be clearly identified on the envelope as either a "Request for Exemption from Tamper-Resistant Rule" or "Request for Stay of Tamper-Resistant Rule." If a firm submits both a

stay and an exemption for the same product, it is requested that each petition be submitted separately in its own envelope clearly marked as set forth above. Further, if a firm submits comments on the final rule, they should be submitted separately to the agency and not combined with either a request for a stay or request for an exemption.

Effective date. The regulations become effective in three steps. The requirement that a tamper-resistant package be used is effective February 7, 1983 for OTC drug products and cosmetics that are the most vulnerable to tampering. The OTC drug products subject to this effective date are: oral, vaginal, and rectal drugs (other than tablets and suppositories), otic drugs, nasal drugs, ophthalmic drugs. A later effective date of May 5, 1983 is provided for oral and vaginal tablets and vaginal and rectal suppositories. The tablet and suppository dosage forms are considered less susceptible to tampering because known methods of tampering are more difficult to apply to tablets and suppositories without creating visible evidence that tampering has occurred. For all products, the label statement requirement and the requirement that the barrier to entry be distinctive are effective May 5, 1983.

There is a third effective date, 1 year from the initial effective date, February 6, 1984, by which time all stocks held for sale (including stocks in retail stores), no matter when packaged, must be in compliance with the requirements for tamper-resistant packaging. This date also applies to imported products. The effective date provisions assure that those products that are most susceptible to malicious adulteration will be the first required to be packaged in tamper-resistant packaging. FDA believes that longer effective dates for those products for which malicious adulteration is less likely will permit manufacturers to comply more quickly with the requirement applicable to the more susceptible products without undue risk to consumers. The later effective date for the label statement requirement and the requirement for a distinctive barrier to entry recognize that these requirements, although important, are not as urgent as the need to assure that tamper-resistant packaging is used, and that it may take more time to arrange for the labeling and package design changes that must be made to comply with these provisions of the regulations.

The time limits selected by FDA also take into account information provided to the agency by the Proprietary Association concerning the ability of the OTC drug industry to acquire the necessary packaging equipment and integrate it into their production systems. Accordingly, a requirement effective immediately or a requirement effective for all products at the end of a comparatively short period of time, such as 3 months, would impose a serious strain on the packaging machinery industry to produce, and on the OTC drug industry and other affected manufacturers to acquire and put into place, the equipment needed to produce tamper-resistant packaging.

Several consequences could be anticipated were the agency to require an early effective date for all products. First, companies unable to meet the requirement would have to discontinue marketing their products after the effective date. Second, it could force industry to compete for scarce resources as if all products presented identical risks. Either result could disrupt the supply of OTC drugs to the consumer and make it difficult for manufacturers of tamper-susceptible products in particular to meet the deadline. The costs of compliance, and thereby the price of OTC drug products to the consumer, would also be unnecessarily high.

FDA concludes, therefore, that the sequential effective dates established by this regulation are reasonable and necessary. It is appropriate for FDA to assure an adequate supply of OTC products at a reasonable price, and it is therefore appropriate for FDA to phase in the requirements of the regulations set forth in this final rule to assure that the supply of these products is not unnecessarily disrupted and that their prices are not unnecessarily increased. That objective can be achieved by deferring the effective date for products that are less susceptible to tampering or less harmful if tampered with. By providing a deferred effective date for less susceptible products, the agency is providing on a categorical basis the relief it would have been likely to grant on an individual basis.

These regulations apply to all affected products produced in retail packaging on or after the effective dates. Applying the same effective date to products produced earlier than the effective date would require immediate withdrawal from the retail shelves of noncomplying products after the 3- or 6-month effective dates, a result that would be impractical and disruptive to health care. Because of the need for the affected industry to avoid further incidents of tampering and the incentive the industry has to maintain consumer confidence in OTC drug and cosmetic products, the agency anticipates that manufacturers will take prompt action to implement the provisions of these regulations even before the mandatory effective dates. FDA believes that, for this reason, the market will be significantly depleted of products in non-tamper-resistant packaging within a relatively short period of time.

However, in order to assure that at some defined future date all products covered by the rule are contained in tamper-resistant packaging (although without the labeling or distinctive design requirement), even to the retail level, the agency is establishing a retail level effective date of February 6, 1984 after which all products packaged before May 5, 1983 must be in compliance with the requirement that they be packaged in tamper-resistant packaging. (Products packaged after the May 5, 1983 effective date must be in compliance with all aspects of the regulations after that date, without regard to the retail level effective date. Products packaged after the February 7, 1983 effective date must be in compliance with the tamper-resistant packaging requirement after that date, without regard to the retail level effective date.) The agency believes that manufacturers will be encouraged to convert their product packaging to the non-tamper-resistant variety sooner if products meeting that requirement of the regulations that are packaged before May 5, 1983 are not subject to the retail level effective date with respect to the labeling and distinctive design requirements. Accordingly, the retail level effective date will not apply to the labeling and distinctive indicator or barrier to entry requirements of the regulations.

The agency acknowledges that it may prove difficult to meet this effective date. In that event, FDA must consider whether removal of all products that are not in compliance as of that date may have an adverse impact on the availability of some products in the marketplace and consequential disruption of health care. It is also possible that the quantity of noncomplying products remaining on the market by this time will be negligible, in which case a retail level effective date may be unnecessary. Because of the uncertainty involved in attempting to estimate the circumstances that will prevail at the time of the retail level effective date, the agency will review the need for such a date and what the date should be after it has had an opportunity to determine the effects of this regulation on the marketplace. Such review will take place long enough before the retail level effective date occurs for any change in that date to be

taken into account by those who will be required to meet it. In addition, FDA will consider requests for stays in the retail level effective date on a case-by-case basis.

After the retail level effective date, products remaining on retail shelves that were packaged before May 5, 1983 that are not packaged in tamper-resistant packaging will be considered adulterated and misbranded. Given the unique circumstances that have made these regulations necessary, FDA will consider all feasible alternatives to dealing with noncomplying products remaining in trade channels.

IV. Legal Authority

Under the Federal Food, Drug, and Cosmetic Act, FDA is authorized to impose requirements necessary to assure that drugs meet the requirements of the act for identity, strength, quality, and purity. Such requirements may be imposed as current good manufacturing practice (CGMP) (21 U.S.C. 351 (a)(2)(B)) and in aid of other statutory requirements relating to product safety and integrity. See, e.g., 21 U.S.C. 351(b) and (c).

Under its authority to specify CGMP's, FDA already requires drug product containers to protect against "foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product" (21 CFR 211.94(b)). That regulation was intended to deal with contamination originating during storage of drug products throughout the chain of distribution up to the point of use by the consumer, including storage by intermediaries, retail outlets, and the consumer. That regulation was not, however, intended to require the use of tamper-resistant packaging. When that regulation was issued, tampering was not regarded as a sufficiently serious problem to justify the imposition of container security measures aimed at safeguarding drug products against contamination from tampering. The recent events involving Tylenol, combined with other recent tampering incidents, make it clear that tampering is a serious problem to which the affected industry must respond. The requirements set forth in FDA's CGMP regulations for pharmaceutical products represent those measures needed to ensure that drugs purchased by the people of this country meet all statutory requirements at the time of purchase. Such measures must now include provision for container and package design that provides protection against intentional product adulteration by means of tampering.

FDA's authority to issue Federal standards for tamper resistant drug packaging is also derived from other provisions of the act relating to drug adulteration. Under section 501(b) of the act, drugs are required to meet applicable compendial standards for strength, quality, and purity. Under section 501(c) of the act, drugs not subject to compendial standards are required to possess the strength, quality, and purity they are represented to have. Because contamination of drugs by tampering causes these requirements to be violated, FDA is authorized to impose packaging requirements reasonably designed to prevent such contamination. The existing regulation requiring the use of seals on ophthalmic products was issued under the authority of section 501(c) of the act. See 21 CFR 200.50(a)(3). That regulation was issued in response to contamination of ophthalmic products at the retail level by persons using the products in the store and then returning them to the shelves. Persons who subsequently bought the products were exposed to injury from contamination of the products caused by this kind of tampering.

FDA is also authorized to issue package security requirements for cosmetics. Such authority is found in sections 601 (a) and (c) and 701(a) of the act. Under section 601(a) of the act, a cosmetic is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users. Under section 601(c) of the act, a cosmetic is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. Section 701(a) of the act authorized FDA to issue regulations for the efficient enforcement of the act.

In the past, FDA has issued regulations requiring the labeling of certain cosmetic products to contain warning statements. In some cases, the statements have been required to warn consumers of the danger of intentional misuse. For example, § 740.11(b)(1) (21 CFR 740.11(b)(1)) requires a warning against the intentional inhalation of certain aerosol propellants. The agency required the warning after it became apparent that the dangerous practice of inhaling propellants had become sufficiently frequent to constitute a hazard of widespread public concern. (40 FR 8012; March 3, 1975.) Intentional tampering is an abusive practice that also presents hazards for consumers of the cosmetic products named in the regulation and, therefore, the agency is requiring the same packaging and warning statements for cosmetic liquid oral hygiene products and vaginal products that it is requiring for certain OTC drugs.

The requirement for a label statement alerting the purchaser to the tamper-resistant feature of a product's packaging is authorized under the cited adulteration provisions and under sections 502(c), 602(c), and 201(n) of the act. The label statement is necessary to assure the effectiveness of the tamper-resistant feature and is an integral part of the tamper-resistant package design. The absence of the label statement thus causes the product to be adulterated. In addition, under sections 501(c) and 602(c) of the act, a product is misbranded if a statement required under other authority in the act is omitted from the product's labeling. Finally, under sections 201(n), 502(a), and 602(a) of the act, a product may be misbranded by reason of the omission of a material fact about the product. The agency believes that omission of a statement alerting the consumer to a packaging feature designed to prevent adulteration would constitute the omission of a material fact, in light of representations made elsewhere in the labeling of a product intended to induce purchase through the implicit representation that the product is not adulterated.

FDA concludes that mandatory standards for tamper-resistant packaging are necessary. The affected industry has shown a commendable interest in improving product security by voluntary means. However, in a matter of such serious public health concern, it is appropriate that the agency assure that all necessary steps will be taken by manufacturers through the issuance of a binding regulation.

Nothing in these regulations relieves any person of the responsibility for compliance with other applicable regulations including the drug CGMP regulations. In particular, major changes in packaging to comply with these regulations may affect compliance with the expiration dating requirements of 21 CFR 211.137. Additional stability studies may be necessary under these circumstances.

Preemptive status of these packaging requirements

FDA intends that the regulations issued in this document preempt State and local packaging requirements that are not identical to it in all respects, including those relating to the use of alternative tamper-resistant packaging systems, the coverage of the regulations within the product categories addressed,

the label statement alternating consumers, exemptions, and effective dates.

As previously discussed, FDA is authorized to assure the safety of drugs and cosmetics marketed in interstate commerce in this country. The manufacturing and distribution system for these products is national in scope and the measures adopted by FDA to regulate this national system should be adequate to safeguard the interests of the entire population. While State and local requirements for products may on occasion be appropriate and necessary, such measures should not interfere with FDA's accomplishing those purposes that are within its Congressionally mandated area of responsibility.

The requirements established by these regulations provide for the use of tamper-resistant packaging for most OTC drug products and certain cosmetics. The requirements become effective on a staggered basis aimed at bringing about the use of tamper-resistant packaging more quickly for those affected products that are most susceptible to tampering or most potentially harmful if maliciously adulterated. The effective dates take into account the availability of packaging machinery, and the ability of manufacturers to acquire and begin to use it, such that the need for consumer protection is met without unnecessary disruption of the supply or increase in the cost of affected products. FDA therefore regards this final rule as providing protection against malicious tampering in the manner most advantageous to consumers. FDA acknowledges the interest of State and local jurisdictions in protecting their citizens from criminal acts involving OTC drug products. The agency believes that this interest is given effect by the regulations issued in this final rule.

State and local requirements for OTC product packaging that differ from those established by this final rule would interfere with the accomplishment of FDA's objectives in several ways. These regulations are intended to allow the use of alternative packaging systems to guard against tampering. A State or local requirement that one or several specific packaging systems be used exclusively would have one of several undesirable effects. First, it would exclude from that market products not using the designated systems. Such an exclusion would curtail the supply of OTC drugs and cosmetic products to the residents of the jurisdiction involved. It would also interfere with competition within that market, with an accompanying potential for higher prices. Second, it could, if the State or local market was big enough, force manufacturers to adopt the State or local standard for products marketed anywhere in the country where that standard was consistent with other State or local standards. This result would effectively negate the FDA regulations set forth in this final rule. It would also force manufacturers to use a limited number of packaging systems with no assurance that such systems are the best adapted to providing tamper-resistance or the most cost-effective packaging system that produces a tamper-resistant package. It would, finally, provoke intense competition among manufacturers for a limited range of packaging equipment capable of producing the complying packaging, thus impeding the conversion of all affected OTC drugs and cosmetics to the tamper-resistant variety. Third, affected manufacturers could be forced to adopt different packaging systems meeting the separate requirements of each jurisdiction, if this were done, product costs and prices would be increased by the need to create different manufacturing and distribution systems adapted to the different requirements prevailing throughout the country.

In addition to these undesirable effects on the distribution and cost of affected OTC drugs and cosmetics and on the ability of the affected industry to convert quickly and efficiently its products to tamper-resistant packaging, State and local drug and cosmetic packaging requirements have the potential for interfering with FDA's ability to enforce the agency's own tamper-resistant packaging requirements. For example, because of differences in interpretation, it is possible that a product that met the Federal requirement would be deemed illegal at the State or local level, or vice versa.

Imposition of State or local packaging requirements prior to the effective dates of these regulations would also hinder the orderly attainment of the objectives that these regulations are intended to achieve. The 3- and 6-month effective dates specified in this document have been established in response to information concerning the availability of packaging equipment and the ability of manufacturers to procure it and integrate it into their manufacturing operations. These effective dates will assure that products are produced in tamper-resistant packaging as soon as possible consistent with an adequate supply of products at a reasonable cost. The retail level effective date, February 6, 1984, for products packaged prior to May 5, 1983 balances the infeasibility of converting the packaging of already manufactured products into tamper-resistant packaging against the consumer's need at some point to be certain that all products for retail sale are contained in such packaging. An earlier retail level effective date, or State or local packaging requirements applicable to the retail sale of products in noncomplying packaging, would potentially undermine the ability of manufacturers to implement these regulations by diverting attention from the effort to bring new packaging into compliance with those regulations. An early requirement for retail level compliance would also disrupt the availability of products to the consumer for an indeterminate period of time.

For these reasons, FDA concludes that, as of the date of publication of this final rule, the requirements imposed by this final rule should be the exclusive means of bringing about the use of tamper-resistant OTC drug and cosmetic packaging and associated labeling. See *Jones v. Rath Packing Co.*, 430 U.S. 519, *reh. denied*, 431 U.S. 925 (1977); *Cosmetic, Toiletry & Fragrance Ass'n v. State of Minnesota*, 440 F. Supp. 1216 (D. Minn. 1977, *aff'd per curiam*, 575 F.2d 1255 (8th Cir. 1978)); *Brookhaven Cable TV, Inc. v. Kelly*, 573 F.2d 765 (2d Cir. 1978) *cert. denied*, 441 U.S. 904 (1979).

Good cause to issue a final regulation

The Administrative Procedure Act and FDA regulations provide that a general notice of proposed rulemaking need not be published in the Federal Register when the agency for good cause finds that "notice and public procedure . . . are impracticable, unnecessary, or contrary to the public interest." (5 U.S.C. 553(b)(3), 21 CFR 10.40(e)(1).) As discussed above, the problems caused by malicious tampering are multiple and pose significant public health concerns. As reports of each new episode of malicious tampering receive wide exposure in the news media, the likelihood of further similar incidents increases. It is clearly in the public interest to move quickly to establish uniform Federal regulatory standards that will enable manufacturers to implement tamper-resistant packaging and labeling requirements as efficiently and expeditiously as possible. Quick action by the agency is vitally necessary to reduce the likelihood that additional tampering will occur or that other innocent purchasers will be harmed. In addition, a rapid response will enhance agency efforts to educate purchasers by alerting them to the problems and will help restore public confidence in the

integrity of the OTC drug and cosmetic products in the marketplace.

The requirements contained in the regulations set forth in this final rule are based on standards and technology suggested by and discussed with representatives of the OTC drug manufacturing industry. Based in part on these discussions and on discussions with representatives from the cosmetic industry, the agency believes that the requirements are reasonable and that the timetable for compliance is attainable.

Therefore, the agency has concluded that because adequate protection of the public health requires that tamper-resistant packaging be implemented as quickly as possible, there is good cause to issue these regulations as a final rule. See generally *Hercules, Inc. v. Environmental Protection Agency*, 598 F.2d 91, 125 (D.C. Cir. 1978).

The agency is providing a 30-day comment period and will review carefully all comments submitted during that period to determine the appropriateness of revisions to this final rule.

V. Economic Considerations

FDA has examined the regulatory impact and regulatory flexibility implications of this final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act. The agency estimates that this final rule will affect about 2 billion retail packages per year. Some of these OTC products (perhaps 10 to 30 percent) are already packaged in ways defined as acceptable, and will need only labeling statements and distinctive indicators or barriers to entry. Many, probably most, of the remaining products would be converted to tamper-resistant packaging even in the absence of this final rule—to reduce actual risks, to restore or sustain consumer confidence, or, in some cases, to comply with new State or local requirements. Therefore, the cost impacts attributable to this final rule are some fraction of the total costs that will be incurred by manufacturers to improve the integrity of their products' packaging.

The 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 sarink 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 to $40 million per year.

Costs for new packaging equipment are not expected to have a significant impact on the average cost per package. Equipment investment outlays would presumably be spread over several years following the effective date, depending on equipment availability (which varies from several months to 2 years) and manufacturer preferences as to packaging systems. Some manufacturers may temporize with the less expensive equipment, until they have decided upon and taken delivery of the equipment they will use in the long run. The cost of packaging equipment varies widely from less than $100 to over $100,000 per unit. When these investments are depreciated over the life of the equipment and the number of packages handled, the average cost per package appears extremely small regardless of the original cost.

The 3- and 6-month effective dates for tamper-resistant packaging may impose some additional cost penalty on manufacturers. If manufacturers cannot install new packaging equipment before the effective date, they could experience a period of market disruptions or high manual packaging costs. The final rule anticipates some difficulty in obtaining delivery of packaging equipment. The provision for petitions for stays of the effective date should largely eliminate cost impacts in these situations. Similarly, the 6-month effective date for labeling statements may impose added costs. The one-time change in labeling for all affected products is expected to cost $5 to $10 million. The agency does not believe that the industry will experience significant costs for stocks of obsolete packaging at the 6-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 that any such returns will be very small in volume, will not occur at the wholesale level, and will be confined to the smallest retail outlets. The agency's stated intent to reconsider this effective date after it has an opportunity to observe the market effects of the final rule supports the conclusion that the cost of obsolete stock returns will be insignificant.

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. Moreover, it is the obvious intention of major industry segments to proceed with tamper-resistant packaging regardless of any regulation. Therefore, the net cost impact attributable to the final rule is far below that which would require a regulatory impact analysis.

Because these regulations are issued as a final rule without being preceded by general notice of proposed rulemaking, a final regulatory analysis under section 604 of the Regulatory Flexibility Act (94 Stat. 1167) is not required. In any event, the rule will not have a significant economic impact on a substantial number of small entities. A comparatively few large firms dominate the OTC drug market with the 20 largest firms accounting for about two-thirds of sales. These large firms will probably utilize the more expensive, high-volume packaging equipment. Moreover, exemptions and petitions for a stay are available to small firms that may have difficulty complying with the provisions of this final rule.

VI. Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(d) (12) and (13) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental statement is required.

List of Subjects

21 CFR Part 211

Drugs—Manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

21 CFR Part 314

Administrative practice and procedure, Drugs.

21 CFR Part 700

Cosmetics, Definitions, Prohibited cosmetic ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (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), Parts 211, 314, and 700 are amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. Part 211 is amended by adding new § 211.132 to read as follows:

§ 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 the 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 must 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)(vii), (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 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 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 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 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 after May 5, 1983 must be in compliance with all aspects of the regulations without regard to the retail level effective date.

PART 314—NEW DRUG APPLICATIONS

2. Part 314 is amended in § 314.8 by revising the first sentence in paragraph (a) (4) (vii) and (5) (xi), by revising paragraph (a) (5) (xii), and by revising the first sentence in paragraph (d) (5) to read as follows:

§ 314.8 Supplemental applications.

(a) * * *

(4) * * *

(vii) A change in container to provide for "special packaging" as defined in § 310.3(1) 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. * * *

(5) * * *

(xi) Changes which provide for "special packaging" as defined in § 310.3(1) 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. * * *

(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.

* * * * * *

(d) * * *

(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.

PART 700—GENERAL

3. Part 700 is amended by adding new § 700.25 to read as follows:

§ 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 substitution of the 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 must 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 of paragraph (b) of this section is effective on Feburary 7, 1983 for each affected cosmetic product (except vaginal tablets) packaged 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 of paragraph (b) of this section is effective on May 5, 1983 for each cosmetic product that is a vaginal tablet packaged 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 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 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 after May 5, 1983 must be in compliance with all aspects of the regulations without regard to the retail level effective date.

Interested persons may, on or before December 6, 1982, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above and between 9 a.m. and 4 p.m., Monday through Friday.

Effective dates. These regulations are effective November 5, 1982, with the following exceptions:

(1) Section 211.132(b) and (c).

(2) Section 700.25(b) and (c).

For the effective dates applicable to the specified sections, see §§ 211.132(g) and 700.25(c). Those sections provide that packaging requirements are effective February 7, 1983 for all OTC drug products subject to this rule (except oral and vaginal tablets and vaginal and rectal suppositories) and for cosmetic liquid oral hygiene products and liquid vaginal products packaged on or after that date. Labeling requirements for all products and packaging requirements for oral and vaginal tablets and vaginal and rectal suppositories are effective May 5, 1983. Products packaged prior to May 5, 1983, and held for sale at the retail level must be in compliance with the tamper-resistant packaging requirement, but not the distinctive indicator or barrier to entry or labeling requirements of the regulations by February 6, 1984.

(Secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1040–1055 as amended, 55 Stat.

851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371))

Arthur Hull Hayes, Jr.,
Commissioner of Food and Drugs.

Richard S. Schweiker,
Secretary of Health and Human Services.

Dated: November 3, 1982.

[FR Doc. 82-30945 Filed 11-4-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 200 and 800

[Docket No. 82N-0332]

Tamper-Resistant Packaging Requirements for Contact Lens Solutions and Tablets.

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing additional requirements for tamper-resistant packaging of contact lens solutions and tablets used to make those solutions. These products are regulated as medical devices because they are accessories to medical devices, i.e., contact lenses. Contact lens solutions and tablets used to make these solutions are, like drugs, vulnerable to malicious adulteration. FDA is revising a regulation that now requires sealed packaging for contact lens solutions and is making conforming amendments in the provisions for opthalmic preparations that are regulated as drugs. FDA is adding to current requirements a new requirement for a distinctive indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering had occurred. Also required is a statement on the labeling of the products to alert consumers to the tamper-resistant feature. This action is taken because of the recent cases of malicious adulteration of over-the-counter drug products that resulted in seven deaths in the Chicago area and the risk of similar episodes with other over-the-counter products.

DATES: The packaging requirements are initially effective on February 7, 1983 for each liquid contact lens solution product packaged on or after that date. The distinctive indicator or barrier to entry and the labeling requirements for all contact lens solution products, as well as the packaging requirements for tablets intended to make such solutions, are initially effective on May 5, 1983. Products packaged prior to May 5, 1983 and held for sale at the retail level must be in compliance with the tamper-resistant packaging requirement, but not the distinctive indicator or barrier to entry or labeling requirements of the regulations by February 6, 1984. Comments by December 6, 1982. For further details see the effective dates information following the text of the regulations.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, National Center for Devices and Radiological Health (HFK-140), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the Federal Register, FDA is publishing a final rule to require tamper-resistant packaging and related labeling for most over-the-counter (OTC) drug products for human use and for certain cosmetics.

FDA is now adding to the medical device regulations, as new § 800.10 (21 CFR 800.10), a current requirement now codified with the drug regulations (21 CFR 200.50) for sealed packaging of contact lens solutions, which are regulated as medical devices. FDA also is adding, in new § 800.12 (21 CFR 800.12), more specific requirements for tamper-resistant packaging and a new requirement for labeling alerting consumers not to purchase the product if the tamper-resistant feature has been altered. The requirements apply to solutions intended for use in cleaning, disinfecting, wetting, or storing contact lenses and to tablets intended to make such solutions. (Salt tablets not intended for such use would be subject to the regulations for OTC drugs.)

The new requirements are similar to those for OTC drugs. Contact lens solutions and tablets used to make these solutions resemble OTC drugs, may be introduced directly or indirectly into the eye, and are marketed at the retail level in the same way as OTC opthalmic drugs. They are, as a result, similarly vulnerable to malicious adulteration.

FDA recognized the susceptibility of ophthalmic preparations to tampering when it promulgated § 200.50(a)(3), which requires all ophthalmic preparations, including contact lens solutions, to have containers or individual cartons that are so sealed that the contents cannot be used without destroying the seal. This regulation was issued in response to contamination of ophthalmic products at the retail level by individuals using the products in the store and then returning them to the shelves, thus exposing those who later purchased the products to injury from contamination resulting from this kind of tampering. Section 200.50 applies to ophthalmic preparations whether regulated as drugs or as devices. When FDA issued this regulation in the Federal Register of October 23, 1972 (37 FR 23105), the agency regulated as drugs solutions used, for example, to clean, disinfect, wet, or store contact lenses and tablets used to make such solutions. Although certain contact lenses ("soft" lenses) were also regulated then as drugs, others ("hard" lenses) were regulated as devices. In 1976, as a part of the Medical Device Amendments (Pub. L. 94-295), Congress both strengthened FDA's authority to ensure that devices are safe and effective and broadened the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)). Under the broadened definition, all contact lenses and their accessories, including solutions, are treated as devices. Despite the change in statutory treatment of contact lens solutions, however, FDA has inadvertently left unchanged in the drug regulations the regulatory requirements in § 200.50, even though some provisions of this section apply to products now regulated as devices. (At one time, a single set of regulations covered drugs and devices. FDA recodified its regulations to establish Subchapter C on drugs (March 27, 1975; 40 FR 12996) and Subchapter H on medical devices (February 13, 1976; 41 FR 6896).)

Although § 200.50 has continued to apply to all contact lens solutions, this regulation alone is not enough. As is explained in the preamble to the rule on OTC drugs, a packaging requirement should be supplemented with a requirement of a distinctive indicator or barrier to entry which, if breached or missing, indicates tampering, as well as a labeling statement to enable consumers to detect tampering through knowledge that a tamper-resistant feature has been incorporated into the package design. The inadequacy of a packaging requirement alone is demonstrated by recent incidents in which ophthalmic OTC drug products subject to § 200.50 may have been maliciously adulterated, with subsequent injury to consumers. A distinctive indicator or barrier to entry, and a labeling statement describing the purpose of the tamper-resistant feature and cautioning against purchase if the feature were broken or absent, might have provided additional security in these cases.

Accordingly, FDA is now removing from § 200.50 those provisions that

pertain to contact lens solutions and tablets used to make these solutions and is establishing these provisions in new § 200.10. FDA also is publishing new § 200.22 applying to these solutions and tablets the same tamper-resistant packaging and labeling requirements as are being applied to OTC drugs. For brevity and efficiency, FDA is incorporating into this rulemaking proceeding the preamble to, and the administrative record of, the final rule on OTC drugs and certain cosmetics published elsewhere in this issue of the Federal Register. FDA also is removing from § 200.50 the original 1972 effective date provisions, which no longer are relevant.

EFFECTIVE DATES: The regulations become effective in three steps. The requirement that a tamper-resistant package be used is effective February 7, 1983 for lens solutions in liquid form, which are more vulnerable to tampering than are tablets used to make these solutions. Because of the requirement in § 200.50 of a sealed package, some of these products already should be packaged in conformity with the new requirement of a tamper-resistant package. An effective date of May 5, 1983 is provided for application of the tamper-resistant package requirement to tablets used to make lens solutions. The tablet dosage form is considered less susceptible to tampering because known methods of tampering are more difficult to apply to tablets without creating visible evidence that tampering has occurred. For all products, the label statement and the requirement of a distinctive indicator or barrier to entry are also effective on May 5, 1983. FDA believes that longer effective dates for those products for which malicious adulteration is less likely will permit manufacturers to comply more quickly with the requirement applicable to the more susceptible products without undue risk to consumers. The later effective date for the label statement and distinctive barrier requirements recognizes that these requirements, although important, are not as urgent as the need for adequate tamper-resistant packaging, and that it may take more time to arrange for the labeling and package design changes that must be made to comply with these provisions of the regulations.

The time limits selected by FDA also take into account information provided to the agency by the Proprietary Association, and relevant to this rule, concerning the capacity of the OTC drug industry to acquire necessary packaging equipment and integrate it into their production systems. As is discussed in further detail in the OTC drug rule published elsewhere in this issue of the Federal Register, making all the new requirements effective immediately or at the end of a comparatively short period of time, such as 3 months, would impose a serious strain on the packaging machinery industry to produce, and on affected manufacturers to acquire and put into place, the equipment needed to produce tamper-resistant packaging.

These regulations apply to all affected products produced in retail packaging on or after the effective dates. Applying the same effective date to products produced earlier than the effective date would require immediate withdrawal from the retail shelves of noncomplying products after 3- or 6-month effective dates, a result that would be impractical and disruptive to health care. Because of the need for the affected industry to avoid further incidents of tampering, and the incentive the industry has to maintain consumer confidence in OTC drug and cosmetic products, the agency anticipates that manufacturers will take prompt action to implement the provisions of these regulations even before the mandatory effective dates. FDA believes that, for this reason, the market will be significantly depleted of products in non-tamper-resistant packaging within a relatively short period of time.

However, in order to assure that at some defined future date all products covered by the rule are contained in tamper-resistant packaging (although without the labeling or distinctive design requirement), even to the retail level, the agency is establishing a retail level effective date of February 6, 1984 after which all products packaged before May 5, 1983 must be in compliance with the requirement that they be packaged in tamper-resistant packaging. (Products packaged after the May 5, 1983 effective date must be in compliance with all aspects of the regulations after that date, without regard to the retail level effective date. Products packaged after the February 7, 1983 effective date must be in compliance with the tamper-resistant packaging requirement after that date, without regard to the retail level effective date.) The agency believes that manufacturers will be encouraged to convert their product packaging to the non-tamper-resistant variety sooner if products meeting that requirement of the regulations that are packaged before May 5, 1983 are not subject to the retail level effective date with respect to the labeling and distinctive design requirement. Accordingly, the retail level effective date will not apply to the labeling and distinctive indicator or barrier to entry requirements of the regulations.

The agency acknowledges that it may prove difficult to meet this effective date. In that event, FDA must consider whether removal of all products that are not in compliance as of that date may have an adverse impact on the availability of some products in the marketplace and consequential disruption of health care. It is also possible that the quantity of noncomplying products remaining on the market by that time will be negligible, in which case a retail level effective date may be unnecessary. Because of the uncertainty involved in attempting to estimate the circumstances that will prevail at the time of the retail level effective date, the agency will review the need for such a date and what the date should be after it has had an opportunity to determine the effects of this regulation on the marketplace. Such review will take place long enough before the retail level effective date occurs for any change in that date to be taken into account by those who will be required to meet it. In addition, FDA will consider requests for stays in the retail level effective date on a case-by-case basis.

After the retail level effective date, products remaining on retail shelves that were packaged before May 5, 1983 that are not packaged in tamper-resistant packaging will be considered adulterated and misbranded. Given the unique circumstances that have made these regulations necessary, FDA will consider all feasible alternatives to dealing with noncomplying products remaining in trade channels.

If manufacturers cannot obtain necessary equipment in time to comply with the effective date provisions, it may be necessary to stay the effective date for particular products to avoid disruption of the market for these products. Stays under the citizen petition procedures in § 10.30 (21 CFR 10.30) may be requested for any aspect of the regulations, including those relating to the label statement and the use of a distinctive barrier to entry.

The agency will accept petitions for stays of the effective date, but only if manufacturers and packers adequately demonstrate that they have taken all reasonable steps to apply tamper-resistant packaging technology to their products, but cannot comply by the effective date or cannot get new labeling printed by the effective date. The showing must include a description of the tamper-resistant packaging technology the petitioner proposes to use; a description of the facilities and

equipment needed to apply that technology; a timetable identifying the date when the technology was chosen, the date when the facilities and equipment will be available for applying the technology to the product, and the date by which the product will be in compliance with the regulations. A lengthy stay will not be granted if the petitioner has selected a technology that will require a substantial period of time to obtain and apply and the petitioner could, without undue expense, adequately comply with the regulation by using another technology. To assist the agency in handling any petition for a stay of the effective date or for an exemption for a covered product, it is requested that the submission be clearly identified on the envelope as either a "Request for Exemption from Tamper-Resistant Rule" or "Request for Stay of Tamper-Resistant Rule." If a firm submits both a stay and an exemption for the same product, it is requested that each petition be submitted separately in its own envelope clearly marked as set forth above. Further, if a firm submits comments on the final rule, they should be submitted separately to the agency and not combined with either a request for a stay or request for an exemption.

Legal Authority; Preemption

The new requirements in § 800.12 for contact lens solutions and tablets, like those that are being moved to § 800.10, are issued under section 501(c) of the act (21 U.S.C. 351(c)). This provision requires devices to possess the strength, quality, and purity they are represented to have. See *Dean Rubber Mfg. Co.* v. *United States*, 356 F. 2d 181 (8th Cir. 1966). Because contamination by tampering of contact lens solutions and tablets could cause the requirements to be violated, FDA is authorized to impose packaging standards and related labeling requirements reasonably designed to prevent such contamination.

Other authority for the regulations is found in sections 502(c), 515, and 701(a) of the act (21 U.S.C. 352(c), 360(e), and 371(a)). Section 502(c) of the act deems a device to be misbranded "If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." Section 515 of the act authorizes the establishment of requirements to provide reasonable assurance of the safety and effectiveness of devices, such as contact lens solutions and tablets, that are classified into class III (premarket approval). Section 701(a) of the act authorizes the promulgation of regulations, such as these, for the efficient enforcement of the foregoing provisions of the act.

State and local requirements applicable to tamper-resistant packaging would be preempted, for the reasons given in the OTC drug document and because of the express preemption provisions for medical device requirements in section 521 of the act (21 U.S.C. 360k).

FDA could also promulgate §§ 800.10 and 800.12 under the authority in section 520(f) of the act (21 U.S.C. 360j(f)) to issue good manufacturing practice regulations. The agency is not relying on section 520(f), however, because it has ample authority under the other provisions cited above. In addition, considering both the need to act promptly to respond to recent tampering incidents and the fact that FDA is merely strengthening a current packaging requirement, the delay that would be entailed in complying with the requirements of section 520(f) of the act of issuing a proposed rule, obtaining advisory committee recommendations, and holding an oral hearing would be unacceptable and unnecessary. Although FDA's current good manufacturing practice regulations (21 CFR Part 820) require device packages to be "designed and constructed to protect the device from adulteration or damage during the customary conditions of processing, storage, handling, and distribution" (21 CFR 820.130), this provision does not specifically address tampering. The current good manufacturing practice regulations are in no way superseded or otherwise affected by this rulemaking.

Good Cause To Issue a Final Regulation

The Administrative Procedure Act and FDA regulations provide that a general notice of proposed rulemaking need not be published in the Federal Register when the agency for good cause finds that "notice and public procedure . . ." are impracticable, unnecessary, or contrary to the public interest." (5 U.S.C. 553(b)(B), 21 CFR 10.40(e)(1).) As discussed above and in the preamble to the OTC drug rule, the problems caused by malicious tampering are multiple and pose significant public health concerns. As reports of each new incident of malicious tampering receive wide exposure in the news media, the likelihood of further similar incidents increases. It is clearly in the public interest to move quickly to establish uniform regulatory standards that will enable manufacturers to implement tamper-resistant packaging and labeling requirements as efficiently and expeditiously as possible. Only by acting quickly can the agency hope to reduce the likelihood that additional tampering will occur or that other innocent purchasers will be harmed. In addition, a rapid response should enhance agency efforts to educate purchasers by alerting them to the problems and should help restore public confidence in the integrity of health care products in the marketplace.

The new requirements are based on standards and technology suggested by and discussed with representatives of the OTC drug manufacturing industry. Based in part on those discussions, which are technologically relevant to the packaging and labeling of contact lens solutions and tablets, the agency believes that the requirements are reasonable and that the timetable for compliance is attainable.

Therefore, the agency has concluded that because adequate protection of the public health requires that the new tamper-resistant packaging and labeling requirements be implemented as quickly as possible, there is good cause to issue these regulations as a final rule. See generally *Hercules, Inc.* v. *Environmental Protection Agency*, 598 F.2d 91, 126 (D.C. Cir. 1978).

The agency is providing a 30-day comment period and will review carefully all comments submitted during that period to determine the appropriateness of the revisions to the final rule.

Economic Considerations

The agency has carefully considered the economic effects of this rule and has concluded that it is not a major rule under Executive Order 12291 and would not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act. Most manufacturers already must comply with an existing regulation (§ 800.50). Although each such manufacturer will have to examine the more specific new packaging requirements to ensure compliance with them, and some may have to improve existing packaging, the costs expected to be incurred by manufacturers to comply with the packaging requirements are expected to be small. Manufacturers of contact lens solutions and tablets will need to comply with the new requirements of a label statement and a distinctive indicator or barrier to entry. The discussion of economic considerations in the preamble to the

OTC drug regulation, published elsewhere in this issue of the Federal Register, is relevant to the economic impact of the new labeling requirements to contact lens solution and tablet manufacturers. Because this provision is issued as a final rule without being preceded by general notice of proposed rulemaking, a final regulatory analysis under section 604 of the Regulatory Flexibility Act (94 Stat. 1167) is not required. In any event, the rule would not have a significant impact on a substantial number of small entities.

FDA has determined under 21 CFR 25.24(d)(13) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 800

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (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)) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Parts 200 and 800 are amended as follows:

PART 200—GENERAL

1. Part 200 is amended in § 200.50 by revising paragraphs (a) and (c), to read as follows:

§ 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 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, 1954, 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.

* * * * *

(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.

PART 800—GENERAL

2. Part 800 is amended by adding new Subpart B, to read as follows:

Subpart B—Requirements for Specific Medical Devices

Sec.

800.10 Contact lens solution; sterility.

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

Authority: 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).

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, 1954, 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.

§ 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 to the public health through the 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 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 or 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. 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 should remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a product subject to paragraph (b) of 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. Other changes in packaging shall be the subject of a supplemental premarket approval application which 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 the manufacturer or packer has obtained an exemption from a 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 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 tablet that is to be used to make a contact lens solution and that is packaged on or after that date.

(2) *Initial effective date for labeling requirements.* The requirements in paragraph (b) of this section for a distinctive indicator or barrier to entry and in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each product subject to this section and packaged 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 product subject to this section that is held for sale at retail level on or after that date that was packaged 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 after May 5, 1983 must be in compliance with all aspects of the regulations without regard to the retail level effective date.

Interested persons may, on or before December 6, 1982 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective dates. These regulations are effective November 5, 1982, with the following exceptions:

(1) Section 200.50 (a)(3).

(2) Sections 800.10 (a)(3) and 800.12 (b) and (c).

For the effective dates applicable to the specified sections, see § 211.132 (published elsewhere in this issue of the Federal Register) and 800.12 (f). These sections provide that the packaging requirements are initially effective on February 7, 1983 for each liquid contact lens solution product packaged on or after that date. The distinctive indicator or barrier to entry and the labeling requirements for all contact lens solution products, as well as the packaging requirements for tablets intended to make such solutions, are initially effective on May 5, 1983. Products packaged prior to May 5, 1983 and held for sale at the retail level must be in compliance with the tamper-resistant packaging requirement, but not the distinctive indicator or barrier to entry or labeling requirements of the regulations by February 6, 1984.

(Secs. 501, 502, 515, 52 Stat. 1049–1051 as amended, 1055–1058 as amended, 90 Stat. 552–559, 579 (21 U.S.C. 351, 352, 360e, 360k, 371))

Arthur Hull Hayes, Jr.,
Commissioner of Food and Drugs.

Richard S. Schweiker,
Secretary of Health and Human Services.

Dated: November 3, 1982.

[illegible]

BILLING CODE 4160-01-M

HHS NEWS

MAR 2 - 1983

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOR RELEASE AT 8:00 A.M., EST
Thursday, November 4, 1982

Claire Correll - (202) 245-6343

HHS Secretary Richard S. Schweiker said today he has formally approved and sent to the Federal Register for publication uniform standards for nonprescription drug manufacturers to follow in providing tamper-resistant packaging for their products--effective within 90 days in many cases.

Manufacturers could choose among various techniques--seals, shrink bands, and bubble or strip packs, for example--but would be required to highlight the barrier with a distinctive design that would be hard to duplicate. Each product would also have to prominently display an advisory that the product should not be purchased or used if the seal or barrier was not intact when the product was bought.

FDA Commissioner Arthur Hull Hayes Jr., M.D., said the regulation "allows manufacturers flexibility as to which methods of tamper-resistant packaging will be used. We realize new methods are being developed all the time, and we want to encourage new protection methods," said Dr. Hayes.

"While it is virtually impossible to make any package tamper-proof, it is possible to manufacture packages in such a way that tampering is much more difficult, and that if a product is tampered with, it can more easily be detected by a careful consumer," Schweiker said. "That is the intent of this regulation."

The regulation is a result of the tampering--the opening and refilling of Tylenol capsules with cyanide after they left the manufacturer--which killed seven people in the Chicago area at the end of September and other reports of product tampering since that time.

The regulation becomes effective in steps. The first effective date, in 90 days, requires tamper-resistant packaging on most nonprescription capsule and

(More)

liquid drugs (including eyedrops), except topical dermatologic products. The new packaging would also be required in 90 days on certain cosmetic products that may be susceptible to tampering, such as mouthwashes.

In 180 days tablets and suppositories--which are considered less susceptible to tampering--would be required to have tamper-resistant packaging, too. The delay is designed to ensure that the more susceptible products, such as liquids and capsules, have priority in obtaining the technology and machinery needed to make them secure.

Also at 180 days, the label statement and the distinctive design for barriers would be required. This delay recognizes the practical difficulties these features may pose, although some manufacturers may be able to beat the deadline by months. In fact some expect to begin marketing products in new tamper-resistant packages within the next few weeks. In 15 months, no over-the-counter drug could be sold without tamper-resistant packaging.

Since the Chicago deaths, FDA and the major manufacturers of nonprescription drugs have been working together to review what technology and machinery is available, and how to most effectively protect the public from product tampering.

"The manufacturers of over-the-counter drugs have been extremely cooperative in moving quickly toward better protection. They have acted responsibly and in good faith, and I believe this regulation will give them the uniform national standards they need," said Schweiker.

# # #

(Effective January 1, 1980)

Sec. 11.46.480. Criminal mischief in the first degree. (a) A person commits the crime of criminal mischief in the first degree if, having no right to do so or any reasonable ground to believe he has such a right,

(1) with intent to cause a substantial interruption or impairment of a service rendered to the public by a utility or by an organization which deals with emergencies involving danger to life or property, he damages or tampers with property of that utility or organization and causes substantial interruption or impairment of service to the public;

(2) with intent to damage property of another by the use of widely dangerous means, he damages property of another in an amount exceeding $100,000 by the use of widely danagerous means; or

(3) he intentionally damages an oil or gas pipeline or supporting facility.

(b) Criminal mischief in the first degree is a class B felony. (§ 4 ch 166 SLA 1978)

Cross reference. — As to liability for destruction of property by minors, see AS 34.50.020.

Am. Jur. reference. — 34 Am. Jur., Malicious Mischief, § 1 et seq.

STATE OF ALASKA
FISCAL NOTE

Revision Date , 1983

I. REQUEST

Bill/Resolution No.: CS for HB #247(Jud.)
Title:..tampering with an item in commerce
Sponsor: Rep. Liska
Requestor: Judiciary Committee

II. FISCAL DETAIL

Agency Affected: Health & Social Services
Program Category Affected: Justice
BRU, Program or Subprogram(s) Affected: Adult Confinement

EXPENDITURES/REVENUES: (Thousands of Dollars)

	FY 83	FY 84	FY 85	FY 86	FY 87	FY 88
OPERATING						
100 PERSONAL SERVICES						
200 TRAVEL						
300 CONTRACTUAL						
400 COMMODITIES						
500 EQUIPMENT						
600 LAND & STRUCTURES						
700 GRANTS, CLAIMS, ETC						
TOTAL OPERATING		*	*	*	*	*
* See Analysis.						
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER (Specify Source)						

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

III. SOURCE OF FUNDS TO OFFSET FISCAL IMPACT OF BILL:

IV. ANALYSIS: Attach a separate page for any Analysis

Prepared By: Roger C. Lange Phone: 465-3376
Division: Adult Corrections Date: April 28, 1983

Approved by Commissioner: Date: 4/28/83
Department: Health & Social Services

Distribution:
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Copy to Office of Management and Budget (for Legislature introduced bills)
Copy to Department (for Governor introduced bills)
Copy to Sponsor
Copy to Requestor (if different from Sponsor)

3/9/83

IV. ANALYSIS

There is no statistical data regarding the activity which would become a crime under this act. The Division has no information regarding the annual number of occurrences, arrests, or convictions for tampering with an item in commerce that is a food, drug, device, or cosmetic where physical injury is intended. Therefore, no estimate can be made regarding the fiscal impact of this proposed legislation.

STATE OF ALASKA
FISCAL NOTE

Revision Date , 1983

I. REQUEST

Bill/Resolution No.: HB 247
Title: "...tampering with...food, drug,..."
Sponsor: Rep. Liska
Requestor: House Judiciary

II. FISCAL DETAIL

Agency Affected: Department of Law
Program Category Affected: Admin. of Jus
BRU, Program of Subprogram(s) Affected: Prosecution

EXPENDITURES/REVENUES: (Thousands of Dollars)

	FY 83	FY 84	FY 85	FY 86	FY 87	FY 88
OPERATING						
100 PERSONAL SERVICES						
200 TRAVEL						
300 CONTRACTUAL						
400 COMMODITIES						
500 EQUIPMENT						
600 LAND & STRUCTURES						
700 GRANTS, CLAIMS, ETC						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	- -
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUND	-0-	-0-	-0-	-0-	-0-	-0-
FEDERAL FUNDS						
OTHER (Specify Source)						

POSITIONS:

FULL-TIME	-0-	-0-	-0-	-0-	-0-	-0-
PART-TIME						
TEMPORARY						

III. SOURCE OF FUNDS TO OFFSET FISCAL IMPACT OF BILL:

IV. ANALYSIS: Attach a separate page for any Analysis

Prepared By: Richard L. Peguss
Richard L. Peguss, Director — Phone: 465-3672
Division: Administrative Services Division — Date: March 31, 1983

Approved by Commissioner: Richard L. Peguss
Norman C. Gorsuch, Attorney General — Date: March 31, 1983
Department: Department of Law

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Copy to Requestor (if different from Sponsor)

STATE OF ALASKA
FISCAL NOTE

Revision Date , 1983

I. REQUEST

Bill/Resolution No.: House Bill No. 247
Title:"..tampering with an item in commerce
Sponsor: Rep. Liska
Requestor: Judiciary Committee

II. FISCAL DETAIL

Agency Affected: Health & Social Service
Program Category Affected: Justice
BRU, Program or Subprogram(s) Affected:
Adult Confinement

EXPENDITURES/REVENUES: (Thousands of Dollars)

	FY 83	FY 84	FY 85	FY 86 (est.)	FY 88
OPERATING					
100 PERSONAL SERVICES					
200 TRAVEL					
300 CONTRACTUAL					
400 COMMODITIES					
500 EQUIPMENT					
600 LAND & STRUCTURES					
700 GRANTS, CLAIMS, ETC					
TOTAL OPERATING		*	*	*	*
CAPITAL					
REVENUE					

* See Analysis.

FUNDING: (Thousands of Dollars)

GENERAL FUND					
FEDERAL FUNDS					
OTHER (Specify Source)					

POSITIONS:

FULL-TIME					
PART-TIME					
TEMPORARY					

III. SOURCE OF FUNDS TO OFFSET FISCAL IMPACT OF BILL:

IV. ANALYSIS: Attach a separate page for any Analysis

Prepared By: Roger C. Lange Roger C. Lange III Phone: 465-3376
Division: Adult Corrections Date: April 1, 1983

Approved by Commissioner: Robert London Smith Date: 4/7/83
Department: Health & Social Services

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3/3/83