# REPORT TO THE CONGRESS

# Lack Of Authority Limits Consumer Protection: Problems In Identifying And Removing From The Market Products Which Violate The Law B 164031(2)

Food and Drug Administration

Department of Health, Education, and Welfare

*BY THE COMPTROLLER GENERAL OF THE UNITED STATES*



SEPT. 14, 1972

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WASHINGTON D C 20548

B-164031(2)

To the President of the Senate and the
Speaker of the House of Representatives

This is our report entitled "Lack of Authority Limits Consumer Protection Problems in Identifying and Removing from the Market Products which Violate the Law." The Food and Drug Administration, Department of Health, Education, and Welfare, is responsible for protecting the consumer from violative products.

Our review was made pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67)

Copies of this report are being sent to the Director, Office of Management and Budget, and to the Secretary of Health, Education, and Welfare

Acting Comptroller General
of the United States

# Contents

## ABBREVIATIONS

| | |
|---|---|
| EPA | Environmental Protection Agency |
| FDA | Food and Drug Administration |
| FD&C Act | Federal Food, Drug, and Cosmetic Act |
| GAO | General Accounting Office |
| HEW | Department of Health, Education, and Welfare |
| USDA | United States Department of Agriculture |

# CHAPTER 1

## INTRODUCTION

The use of poisonous preservatives and dyes in foods and the cure-all claims for worthless and dangerous patent medicines led to the enactment of the Federal Food and Drugs Act of 1906 (21 U.S.C. 1-5, 7-15). The 1906 Act was the first step taken to prevent the sale of misbranded and adulterated foods and drugs in interstate commerce. The Food and Drug Administration's authority has been expanded several times since 1906 to include many other consumer products. The Food and Drug Administration (FDA), headed by a Commissioner, is an agency within the Department of Health, Education, and Welfare (HEW). FDA activities are carried out principally through its headquarters and 19 district offices.

The Congress enacted the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301), and the Federal Hazardous Substances Act, as amended (15 U.S.C. 1261), to protect the consumer from adulterated, misbranded, ineffective, or potentially harmful products. Although industry has overall responsibility for insuring that its products are safe and effective, the Congress gave FDA the responsibility for protecting the consumer through enforcement of the statutes.

The Federal Food, Drug, and Cosmetic Act (FD&C Act), defines FDA's regulatory activities for foods, drugs, medical devices, and cosmetics. The act prohibits the introduction of, or delivery of, adulterated, misbranded, or illegally marketed products for introduction into interstate commerce. Adulterated refers to defects in the ingredients or the conditions under which products are processed or packed. Misbranded refers to false or misleading labeling or packaging. Illegally marketed refers to new drugs which have not been approved by FDA for safety and efficacy, as required by the FD&C Act. (In this report adulterated, misbranded, or illegally marketed products are identified as violative products.)

FDA's ability to protect the consumer depends largely on its authority to identify and quickly remove from the market products suspected or known to be violative. FDA

identifies such products by inspecting the firm's facilities and by testing the finished products.

Section 704 of the FD&C Act provides FDA inspectors authority to visually inspect the manufacturing practices, methods, facilities, and conditions under which products are manufactured, processed, or packed. For prescription drugs (but not for drugs which may be purchased without prescription), FDA's authority also extends to a review of production control, quality control, formula, and shipping records, as well as complaint files. These records are used by FDA in the course of its inspections. They are used also to identify and locate products suspected or known to be violative.

Production control records show the step-by-step manufacturing process for each product and can be of great value to inspectors trying to isolate a product containing raw materials suspected or known to be violative or produced under a defective manufacturing process. Quality control records are used to determine whether a firm is maintaining appropriate safeguards for such things as product purity, potency, and stability in its manufacturing process.

The formula is the recipe for the product. It is a complete list of ingredients and the weight or measurements for each ingredient, together with the specifications for combining the ingredients and the conditions and procedures for manufacturing the product. Access to the formula provides FDA inspectors with information to identify the specific ingredients and processes which are supposed to be used and to identify any ingredients or processes which might cause a violative product.

Shipping records enable FDA to determine the specific shipping destinations and indicate whether FDA has regulatory jurisdiction, which extends only to products received or shipped in interstate commerce. Complaint files can give FDA leads on potentially harmful products.

FDA has two methods--seizures and recalls--available for removing products suspected or known to be violative from the market. Seizures are authorized under section 304 of the FD&C Act but require a civil court action and are

consequently limited to the specific quantity and location of products identified in the seizure complaint.

Recalls of products must be made by the voluntary action of the manufacturer. FDA presently has no recall authority. Because recall actions are voluntary on the part of the manufacturer, FDA cannot control delays in initiating the action.

Both seizures and recalls require time to be initiated Although section 302 of the FD&C Act provides FDA with authority to seek injunctions to restrain violations of the act, it does not provide FDA with authority to detain products suspected or known to be violative.

FDA also has responsibility for consumer products other than foods, drugs, medical devices, and cosmetics. The Federal Hazardous Substances Act prohibits interstate shipment of household substances and children's articles which do not contain adequate warning labels or which are hazardous regardless of cautionary labeling. The act defines as hazardous such household substances as chemicals or mixtures of chemicals which are toxic, corrosive, irritant, flammable, or which may cause substantial personal injury or illness. FDA's inspection and enforcement authority under this act is similar to that under the FD&C Act. Also techniques used to inspect and remove misbranded products or hazardous substances are similar to those used for foods, drugs, cosmetics, and medical devices. In this report, misbranded products or products which are considered hazardous, regardless of cautionary labeling under the Federal Hazardous Substances Act, are also identified as violative products.

Our review was directed at FDA's ability to remove products suspected or known to be violative from the market. We reviewed applicable legislative history and FDA's regulations, policies, and practices for removing such products. We also examined FDA's records and files pertaining to fiscal year 1970 refusals of access to firms' records and pertaining to fiscal year 1971 seizures and recalls.

We performed our review at FDA district offices in Detroit, Michigan; Philadelphia, Pennsylvania; and San Francisco, California; and at FDA headquarters in Rockville,

Maryland. We interviewed officials from FDA, the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), the Federal Trade Commission, the U.S. Attorney's Office, the U.S. Marshal's Service, and certain State agencies in California, Pennsylvania, and Michigan. We also discussed our review with 20 firms and five trade associations from the food, drug, and cosmetic industries.

## CHAPTER 2

## LIMITED AUTHORITY FOR ACCESS TO RECORDS

Accomplishment of FDA's consumer protection responsibilities is largely dependent upon FDA's ability to identify and remove products suspected or known to be violative from the market. To carry out this responsibility, FDA must obtain information from the manufacturers' records that will assist in identifying violative products and shipping destinations. Except for prescription drugs, present law does not require firms to provide FDA access to this information and, although most firms cooperate with FDA in this regard, many firms have been unwilling to voluntarily allow FDA such access. Consequently FDA may be unable to obtain needed information and may be prevented from identifying and removing violative products from the market.

During fiscal years 1969 through 1971, 3,300 firms refused to cooperate with requests by FDA inspectors on over 10,000 occasions, including about 7,900 denials of recorded information. The types of records refused and the number of refusals during this period are shown in the following table.

| Records refused | Number | Percent |
|---|---|---|
| Formula data | 4,575 | 46 |
| Production and quality control records | 1,508 | 15 |
| Shipping records | 1,257 | 13 |
| Complaint files | 589 | 6 |
| Total | 7,929 | 80 |
| Other refusals (primarily taking of pictures) | 2,080 | 20 |
| Total | 10,009 | 100 |

These statistics represent only part of the problem. In addition to outright refusals, FDA officials have informed us that some firms provide only partial data or delay providing the requested data to FDA inspectors. The officials informed us also that as a consequence of repeated refusals of data, some FDA inspectors have stopped asking for access to needed information.

## FDA EFFORTS TO PROTECT CONSUMER HAMPERED

In a 1968 report to the Office of the Secretary of the Department of Health, Education, and Welfare, FDA officials stated that:

> "Often an FDA inspector, during the course of an inspection, observes something that indicates that a violation of law is occurring or that violative goods are being held in the plant. But unless he is voluntarily shown control records or other relevant data, he can neither confirm nor disprove his suspicion. And he is usually not shown these records. Before samples can be taken and analyzed and a seizure complaint prepared if needed, the suspected goods are often already on their way to retailers or even in the hands of consumers."

In fiscal year 1970 FDA inspectors in the three district offices which we visited reported that they were refused access to records during 398 inspections of 319 firms. We reviewed case files of 290 inspections made at 235 firms.[1] We found that refusals of access to firms' records prevented FDA from (1) removing products suspected or known to be violative from the market and (2) evaluating firms' production and quality control procedures affecting the quality of their products. Such information is needed by FDA to determine whether to initiate court action for seizure or whether to ask for voluntary recall.

### Refusals delay or prevent actions

For 45, or 16 percent, of the 290 cases reviewed, FDA had indications from other sources that the products involved may have been violative.

--In 34 of the cases, FDA did not or could not pursue the matter further because of insufficient information,

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[1]The cases selected for review represent the first inspection at each of the 235 firms during which FDA encountered refusals and subsequent followup inspections at certain of the firms.

unavailability of the product, or the minor nature of the violations.

--In nine of the remaining 11 cases, FDA's efforts to take removal actions were delayed or prevented because the firms maintained their position to refuse FDA inspectors access to information.

Two examples follow.

Example A--A manufacturer of a liquid drain opener refused to provide FDA with shipping records which were needed to show whether the product was shipped in interstate commerce and, therefore, whether the product was under FDA's jurisdiction.

FDA contended that the product violated the Federal Hazardous Substances Act because it did not have an adequate warning on the label. FDA had received several complaints that the product has caused skin burns. One consumer complained that she had suffered serious facial scarring because the product spontaneously exploded when she poured it into her kitchen drain. Had she not been wearing glasses, she might have been permanently blinded. Despite these injuries, the firm refused to cooperate with FDA.

The FDA district office attempted to locate a sample which had been shipped interstate by obtaining consignee names from a trucking company and by requesting another FDA district office to try to locate the product. This attempt was unsuccessful, and FDA was unable to take action to remove the product from the market.

Example B--A firm which processed walnuts refused to provide FDA with shipping data, even though FDA had found that some of the walnuts at the firm were contaminated with filth and Escherichia coli--a bacteria found in the intestinal tract of warmblooded animals and an indicator of fecal contamination. After notifying FDA officials in another State, a sample of the firm's walnuts was collected and was found to be contaminated. As a result, FDA removed 36 cases of walnuts at this location. An FDA official advised us that the firm's refusal to provide shipping data delayed the eventual removal of the contaminated product from the market in the one location and prevented FDA from removing the

product from other locations and thereby hampered FDA's ability to protect the consumer.

Refusals delay or prevent FDA evaluation of firms' production and quality controls affecting the quality of products

Refusals hampered FDA's inspection efforts in 68, or 23 percent, of the 290 inspection cases we reviewed by delaying or preventing FDA from obtaining information needed to evaluate the firms' production and quality control procedures affecting the quality of their products. In 36 cases FDA performed additional work attempting to obtain the refused information. Following are two examples of refusals which significantly hampered FDA's inspection efforts.

Example C--A bakery made coconut pies with eggs obtained from a supplier whose eggs had been found to contain salmonella (harmful bacteria which can cause illness and even death). In addition to taking action against the egg supplier, FDA requested the bakery's quality control records which were supposed to show the results of testing pies for salmonella. These records were needed because the pies (the only product in which the suspected contaminated eggs were used) had already been distributed.

The bakery refused FDA access to these records, and FDA was unable to determine whether the pies contained salmonella. In addition, FDA was not able to complete an important part of its inspection--evaluation of the firm's procedures for testing products for salmonella. In fact, FDA could not even determine whether tests for salmonella had been performed.

Example D--A firm which manufactures chemicals used in medical diagnoses refused to provide FDA access to its records which included information on products being recalled by the firm. FDA inspectors had estimated that 20 products were being recalled. After allowing FDA to review the files for four of the recalled products, the firm refused further access to its files. Although three FDA inspectors spent 197 hours trying to identify all the products which the firm was recalling, no information on the estimated 16 remaining products could be obtained. The four products identified were being recalled for the following reasons.

| Product | Reason |
| --- | --- |
| Uric acid set | Decomposition resulting in inaccurate readings |
| Serum iron set | Visible mold growth |
| Salicylic acid | Defective |
| Cholesterol set | Labeling error |

FDA officials stated that, because the defects in the products could lead to inaccurate medical diagnoses, all district offices were requested to check on the effectiveness of these recalls.

PRECEDENCE EXISTS FOR ACCESS-TO-RECORDS AUTHORITY

Several Federal agencies have authority to review records relating to the production and distribution of products under their regulatory responsibility. For example, the Federal Meat Inspection Act, as amended (21 U S C 601), requires meat processors to maintain records and give USDA inspectors access to all records bearing on the quality and distribution of meats. The Wholesome Poultry Products Act (21 U S.C. 451) also requires firms to open their facilities and records to examination by USDA inspectors.

Access to records is also authorized by law for the Department of Transportation when inspecting automobiles and automobile tires for safety. In addition, the proposed Federal Environmental Pesticides Control Act of 1972 (H R. 10729) proposes expanded access-to-records authority for use by EPA in controlling pesticides. This bill passed the House of Representatives in November 1971, was approved by the Senate Committee on Agriculture and Forestry in April 1972, and is currently awaiting final Senate action. Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S C 135-135k), EPA already has authority for access to all records showing the delivery, movement, or holding of pesticide products, including quantities of shipments, dates of shipment and receipt of goods, and names of consignors or consignees of shipments. The proposed legislation would provide EPA with additional authority for plant inspection.

In addition, some States have laws which require firms to provide State officials with access to records. California, for example, has a law which requires firms to provide State inspectors with complete access to all records bearing on the quality of a product. Pennsylvania law authorizes its food and drug office access to firms' quality control records and shipping data.

The need for FDA to have access to records was recognized in 1962 when the FD&C Act was amended to require firms which manufacture, process, package, or hold prescription drugs to provide access to records, files, papers, processes, controls, and facilities bearing on whether such drugs are adulterated or misbranded

The Secretary of HEW, in a 1963 letter to the Speaker of the House of Representatives, submitted a legislative proposal to give FDA authority for access to records concerning all products covered by the FD&C Act. The President, in a 1964 message to the Congress, reiterated this request, stating that FDA lacked the needed authority to fully inspect the factories in which products were produced.

FDA officials have stated that access-to-records authority is essential if FDA is to provide consumers with the protection intended by the Congress. FDA officials told us that the lack of cooperation by some firms had increased the cost of inspections or had made them ineffective.

On January 19, 1972, the proposed Pure Food Act of 1972 (H R. 12478) was introduced in the House of Representatives. This bill would amend the FD&C Act to give FDA access to all records for food commodities.

## INDUSTRY AND MANUFACTURING ASSOCIATION COMMENTS

During our review we discussed FDA's authority with officials of 20 food, drug, and cosmetic firms. We also discussed our review and tentative conclusions with representatives of five manufacturing associations. Comments from these officials varied--some agreed that FDA needed additional access-to-records authority; while others disapproved of FDA's access to any records. A major concern of some officials was the protection of trade secrets and formulas from their competitors. Other industry officials, however, told us that this was not a valid concern. The majority of the firms whose officials we interviewed had provided FDA information, including some trade secrets, without any problems.

Another concern expressed by some officials was that additional authority would allow FDA to require firms to provide information without justification or cause. Other officials, however, stated that increasing FDA's access to records would not affect the amount of information they were providing FDA.

An official of a drug manufacturer told us that some firms were not as cooperative as his firm in providing FDA

access to records. He explained that, because his firm provided FDA access to records, it ran a greater risk of having products seized. He believed that all firms should be required to provide FDA the same types of information.

An official from another firm stated that his firm cooperated with FDA because the firm believed it was responsible for complying with more than the minimum legal requirements. He said that some firms used the specific language of the law to prevent FDA from making a complete inspection

FDA, acting on a suggestion by the National Canners Association, published a proposal in the November 12, 1971, Federal Register, which states that FDA personnel should be permitted to inspect canning firms' processing records These records are needed, the proposal states, to insure that adequate processing and coding of low-acid canned food were performed As of May 8, 1972, comments on the proposal were being considered before inclusion in the Code of Federal Regulations.

## CONCLUSION

The lack of authority to review records relating to the production and distribution of all products under FDA's responsibility severely hampers FDA's ability to identify and remove from the market products suspected or known to be violative; thus, consumers are exposed to an increased risk of using such products. We believe that there is a need for legislation giving FDA access-to-records authority--similar to the authority FDA now has for prescription drugs--for all products under its consumer protection responsibility

HEW had prepared legislation for such access-to-records authority and submitted it to the Congress on only one occasion--in 1963--9 years ago. Because industry refusals may prevent FDA from identifying and removing products suspected or known to be violative from the market, we believe the Secretary of HEW should again seek legislative changes to the FD&C Act and the Federal Hazardous Substances Act to provide FDA with expanded access-to-records authority.

## RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary of HEW propose legislative changes to the FD&C Act and the Federal Hazardous Substances Act to provide FDA with authority to examine records and data related to the production and distribution of products under FDA's responsibility.

HEW advised us that it was giving serious consideration to the inclusion of our proposal in its legislative program for the Ninety-third Congress. (See app. I.)

## RECOMMENDATION TO THE CONGRESS

To improve FDA's ability to protect the consumer from all products suspected or known to be violative over which FDA has responsibility, we recommend that the Congress consider amending the FD&C Act and the Federal Hazardous Substances Act to provide FDA with needed access-to-records authority

## CHAPTER 3

## NEED FOR AUTHORITY TO DETAIN PRODUCTS

FDA's lack of detention authority--coupled with the slowness of seizure actions--seriously hampers FDA's efforts to protect the consumer from products suspected or known to be violative.

FDA has authority under existing law to seek court injunctions prohibiting an act by a firm or individual; however, FDA has no authority to temporarily detain products suspected or known to be violative Further, because the seizure process is a civil court action involving several levels of review, the seizure process always takes a number of days before a product legally can be seized and taken off the shelf As a result of these limitations, FDA has been unable to prevent substantial quantities of products suspected or known to be violative from reaching the public

### SLOWNESS OF SEIZURE ACTIONS

Seizure actions are initiated by FDA after analysis of a product or examination of the conditions under which the product was manufactured, packed, or repacked indicates that the product violates the FD&C Act or the Federal Hazardous Substances Act. Usually an FDA district office collects and analyzes a sample of the product to confirm that the product is violative and then recommends seizure action to FDA headquarters. If headquarters approves the recommendation, it requests a U S. Attorney to initiate seizure action in the appropriate Federal District Court

After a seizure warrant is issued, a U.S. Marshal presents it to the firm and has the product removed from the market This procedure takes time, and considerable delay often results between the date the FDA inspector identifies the problem and the date the U S. Marshal executes the seizure

Our review of 88 seizures--for which we could determine the time required to seize the product--showed that the average time required to remove a product from the market

was 54 days The following table shows the average time required at each major action level

| Action level | Average number of days |
|---|---|
| FDA district office | 22 |
| FDA headquarters | 14 |
| Department of Justice (note a) | 18 |
| Total | 54 |

[a]Includes the Federal District Court's time and the U S Marshal's time to seize the product

An FDA official advised us that delays at the district level were generally due to the lack of resources and equipment to complete the analyses of samples He told us that, when large numbers of samples were collected, a backlog could develop Our review of five seizure actions confirmed that delays resulted because of the limited manpower and laboratory facilities needed to make the analyses.

Delays are also encountered at FDA headquarters in using the mail and in the handling of correspondence by the mailroom and clerical staffs. For the five seizure actions reviewed, we found that there was an average delay of 10 days between the time the correspondence was mailed from the district office and the time it was received by the proper officials at FDA headquarters.

FDA has recognized the need for additional resources to improve the processing of seizure actions FDA's proposed budget for fiscal year 1973 includes a request for major increases in dollars and manpower resources, which should assist in expediting FDA laboratory analyses and processing of seizures Some minimum amount of laboratory time will always be needed to perform an analysis of a product For example, the laboratory time required to test foods for salmonella is 7 to 10 days, whereas testing the sterility of drugs requires a minimum of 14 days.

Limited staffs, higher priority work, and problems in preparing legal paperwork also cause delays at the U.S Attorney's Office and the U S. Marshal's Service after FDA has requested the seizure Officials of both a U S Attorney's Office and a U S Marshal's Service told us that anticipated additional increases in staffs should reduce the time required to take seizure actions

## Impact of delays

The impact of delays on the effectiveness of seizures can be seen in the following analysis of 21 seizures from one district

| Number of seizures | Days delayed | Percent of product seized |
|---|---|---|
| 1 | 11 to 20 | 93 |
| 4 | 21 to 30 | 74 |
| 3 | 31 to 40 | 69 |
| 13 | over 40 | 56 |

As the delay increases, the amount of the product reaching the consumer increases

Our review of 91 seizure actions initiated by three FDA districts during fiscal year 1971, for which we could determine the percent of product seized, showed that on an average only 69 percent of the amounts of products identified for seizure were actually seized The remaining quantities were apparently sold to the public

The following table shows our analysis of the percentage of products removed from the market for the 91 seizure actions reviewed

| Number of seizures | Percent of seizures | Percent of product removed |
|---|---|---|
| 16 | 18 | 0 to 10 |
| 12 | 13 | 11 to 50 |
| 7 | 8 | 51 to 70 |
| 12 | 13 | 71 to 90 |
| 44[a] | 48 | 91 to 100 |
| 91 | 100 | |

[a]Includes several seizure actions where State detentions or voluntary holds by the firms were used to detain the products until removed from the market

As noted in the above table, 16 seizures, or 18 percent, removed 10 percent or less of the products identified for seizure

The slowness of seizures and the lack of detention authority can pose a serious health problem to the public Some examples follow

Example E--A firm stored fifty-one 100-pound bags of flour under insanitary conditions, and the flour became contaminated with filth. An FDA inspection at the firm showed that rodents had gnawed into the bags and that rodent urine and excreta pellets were on the bags The firm agreed to voluntarily hold the 51 bags, pending FDA's analysis and completion of the seizure action The seizure action took 47 days Because FDA could not detain the flour during this period, only 21 bags, or 41 percent, were still available for seizure at the time action was taken The other bags were apparently sold, contrary to the firm's agreement

Example F--FDA attempted to seize 3,960 capsules of a drug which contained thyroid, because the firm marketed this drug without obtaining FDA's approval of a new drug application. The approval is required by FDA to insure that all new drugs have been properly tested for safety and effectiveness Also an FDA study showed that thyroid products were ineffective in the treatment of obesity--their intended use The study of products containing thyroid and thyroid combinations was conducted because of numerous injuries and deaths attributable to their use. The seizure action took 30 days, and, because FDA did not have authority to detain products, all the capsules were sold before they could be seized.

Example G--A food firm manufactured and packaged noodles under insanitary conditions. FDA's inspections revealed that the noodles were being processed in an insect- and rodent-infested plant. Insect parts and rodent hairs contaminated the noodles. FDA attempted to seize 5,436 packages of noodles, but the seizure action took 33 days and only 684 packages were actually seized According to FDA officials the remaining 4,752 packages were apparently sold to the public

## EFFECTIVENESS OF AND PRECEDENCE FOR DETENTION AUTHORITY

We found that, in some seizure actions, FDA requested a State or local official to use his embargo authority to detain products pending removal. In those cases the percentage of the product removed from the market was significantly increased. We noted that 34 States had embargo authority which authorized their inspectors to detain questionable products until they were proven safe or removed from the market.

We reviewed seven seizure actions where FDA requested the States or local officials to detain the product. In five of the actions, 100 percent of the products identified for seizure were removed; in the other two actions, 97 percent and 45 percent of the products were removed. We believe that the use of embargo authority resulted in a significant improvement over cases where embargo authority was not used and that having such authority could improve FDA's consumer protection activities.

FDA has stated that using State and local detention authority in lieu of Federal authority is not satisfactory because:

--It results in duplication of effort. Although the FDA inspector has identified a problem, the State inspectors must also observe the problem.

--FDA cannot always contact State officials when necessary.

--Some States have no, or only limited, detention authority.

FDA has stated also that the lack of authority to detain products has been detrimental to effective enforcement of consumer protection laws and has resulted in the sale of defective products.

We note that FDA already has detention authority for meat, poultry, and eggs only under section 409 of the Wholesome Meat Act (21 U.S.C. 679), section 24 of the Poultry

Products Inspection Act (21 U S C. 467), and section 23 of the Egg Products Inspection Act (21 U.S.C. 1052). USDA also has detention authority under these same acts. USDA officials have advised us that detention is a valuable tool and is used extensively in the enforcement of these acts. According to the officials, the 20-day detention period authorized by law allows USDA time to analyze the product and to prepare sufficient documentation to execute a seizure action without the risk of having some of the defective product sold to the public.

In this regard we noted that pending legislative proposals, such as the proposed Pure Food Act of 1972 (H.R 12478), if enacted, would amend the FD&C Act to give FDA detention authority for food commodities.

The need for detention authority has also been recognized for use by EPA. Under the proposed Federal Environmental Pesticides Control Act of 1972 (H R. 10729), EPA would be authorized to stop the sale and distribution of pesticide products which are violative EPA officials stated that this provision was important to the successful enforcement of the EPA pesticide control program

## INDUSTRY AND MANUFACTURING ASSOCIATION COMMENTS

During our review we discussed the need for detention authority with officials from 20 firms. We also discussed our review and tentative conclusions with officials from five manufacturing associations. Although some of the officials agreed that detention authority was necessary, others were concerned with how FDA would implement this authority. The officials raised the following questions concerning the use of detention authority by FDA.

1. What scientific basis would be needed to justify the use of detention authority?

2. Who would be able to invoke detention authority?

3. When would detention be used--for serious hazards only, or for all violations?

4. What would be the maximum time products could be detained, especially perishable products which would have to be destroyed if detained too long?

5. What would be the penalty for violating the detention?

We recognize that these questions have merit and believe they should be considered in establishing detention authority.

## CONCLUSION

FDA's lack of detention authority--coupled with the slowness of seizure actions--seriously hampers consumer protection. As a result of these limitations, FDA is unable to prevent substantial quantities of products suspected or known to be violative from being sold to and consumed by the public.

Both FDA and the Department of Justice have recognized the need for improving the speed of seizure actions, and both have requested additional manpower and resources for reducing the time required to take seizure actions.

Even with additional resources, detention authority is needed because the seizure process always takes a number of days to remove products from the market and because, during this time, products suspected or known to be violative should not be distributed to the public. Therefore we believe that FDA should have authority to temporarily detain products.

The House of Representatives is now considering legislative proposals, such as the proposed Pure Food Act of 1972, which, if enacted, would provide FDA with detention authority for food commodities. We believe that this authority should extend to all products under FDA's responsibility.

## RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary of HEW propose legislative changes to the FD&C Act and the Federal Hazardous Substances Act to provide FDA with authority to detain

products under FDA's responsibility that are suspected or known to be violative.

HEW advised us that it was giving serious consideration to the inclusion of our proposal in its legislative program for the Ninety-third Congress. (See app. I.)

## RECOMMENDATION TO THE CONGRESS

To improve FDA's ability to protect the consumer, we recommend that the Congress consider amending the FD&C Act and the Federal Hazardous Substances Act to provide FDA with the authority to detain products.

## CHAPTER 4

## LIMITED AUTHORITY TO REMOVE PRODUCTS

The methods available to FDA for removing products suspected or known to be violative from the market--seizures and recalls--are often not effective. Seizure actions, besides being slow (see ch. 3), are limited in scope, and recalls--being voluntary--are not enforceable by FDA. As a result, the consumer is frequently exposed to products which should have been removed from the market.

### SEIZURES LIMITED IN SCOPE

Seizure actions are limited to the specific quantity and location of a product identified in the complaint filed by the U S Attorney. FDA must identify the quantity of a product at each location and recommend a separate seizure action for each location. Removing a product from the market is thus very difficult after it has been distributed nationally, as illustrated by the following example.

> Recently, a food firm found that some of its canned products contained botulism (a deadly poison). Had FDA been required to seize the product at each location, over 25,000 separate seizure actions would have been needed. The firm initially agreed to voluntarily recall the product, and seizure actions were generally not needed. However, the firm was unable to honor its agreement because of financial problems and FDA--despite the intense cooperation from other concerned public and private interests in removing the product from the market--still found it necessary to seize the product at 100 different locations.

Needless to say, such a large number of seizure actions was inefficient but was necessary in the absence of better legal authority to remove products from the market. Because of the difficulties involved in seizure actions, FDA has encouraged voluntary recalls as a means of removing products suspected or known to be violative from the market.

## VOLUNTARY RECALLS NOT ENFORCEABLE

A voluntary recall is an action taken by a firm, at the request of FDA or on its own initiative, to remove a product suspected or known to be violative from the market. When recalling a product, the firm involved assumes full responsibility for removing the product. As a result, manufacturers often decide whether or not to initiate a recall and often initiate a recall without notifying FDA. In contrast to seizures, neither FDA nor U S Attorneys and Marshals are directly involved. To the extent possible, however, FDA monitors the firm's effectiveness in removing the product from the market. In fiscal year 1971 FDA monitored over 1,900 recalls.

We were advised by FDA that, to make certain that violative products are removed from the market, manufacturers should be required to notify FDA when they discover such products so that FDA would be in a position to determine the nature and extent of any hazard and to monitor all recalls.

When quickly and effectively implemented, voluntary recalls usually remove greater quantities of the violative products in less time than seizure actions. The firm involved can readily identify the location of the product and advise its customers and consignees that the product should be returned at the firm's expense. Most important, however, is that the recall can be nationwide in scope rather than limited to a specific quantity at a specific location, as is the case with a seizure.

Voluntary recalls do have a significant disadvantage in that there is no statutory authority for such removal actions. Because FDA cannot enforce recalls, they have become a matter of negotiation between industry and FDA and thus can be delayed or ineffectively performed by the firm involved. If FDA is not satisfied with the progress of a recall, seizure action is the only alternative provided under existing law to remove a product from the market. FDA officials told us that seizures were often necessary because firms did not voluntarily remove products suspected or known to be violative from the market.

Our review of 142 recalls monitored by three FDA districts during fiscal year 1971 showed that 106 of them were initiated at FDA's request. For the FDA-initiated recalls, an average of 15 days passed before the firm acted on FDA's request to remove a product from the market. Further, 23 percent of the recalls required more than 25 days to initiate action and in these cases we found that an average of 38 percent of the product was sold during the delay.

For 111 of the 142 recalls, we were able to determine (1) the number of days the recall action was delayed by the firm after it learned of the problem and (2) the percent of the product removed. The following table illustrates the relationship between the length of the delay and the percentage of the product removed from the market.

| Number of recalls | Percent of recalls | Days delayed | Percent of product removed |
|---|---|---|---|
| 70 | 63 | 0 to 10 | 44 |
| 15 | 13 | 11 to 20 | 32 |
| 12 | 11 | 21 to 30 | 32 |
| 14 | 13 | over 30 | 21 |
| 111 | 100 | | |

As shown, the success of a recall depends on the speed with which it is initiated.

The following two examples show that, once identified, significant amounts of a product suspected or known to be violative are still reaching the public because of delays by firms in taking recall actions.

Example H--FDA notified a drug firm on April 27, 1971, that the production of one of its drugs, digitalis (a heart stimulant), was superpotent and was considered a potential health hazard. Although FDA had tested the drug, the firm requested time to retest and perform its own analysis. After 111 days and an appeal to the firm by the Deputy Associate Commissioner for FDA, the firm agreed on August 16, 1971, to recall the superpotent drug. However, this delay made the recall less effective, because about 84,000 pills,

or about 42 percent of the amount distributed, were not recovered FDA officials advised us that seizure of the drug was not practical because of its national distribution.

Example I--A firm produced a prescription drug that did not meet Federal standards for dissolution. FDA tests of the drug showed that the dissolution range was only between 5 and 39 percent compared with the 60-percent minimum dissolution rate required by the Federal standard. FDA considered this defect to be a moderate-to-serious health hazard. FDA notified the firm of the problem on March 19, 1971. The firm initiated the recall 55 days later. According to the firm's estimated consumption rates, this delay permitted about 75,000 of the tablets to be sold to the public.

## INDUSTRY AND MANUFACTURING ASSOCIATION COMMENTS

During the course of our review we discussed the need for recall authority with officials of 20 firms. We also discussed our review and tentative conclusions with officials from five manufacturing associations. Most officials agreed that the quick and complete removal of hazardous products is important to protect the consumer. However, several officials were concerned about how FDA would implement recall authority. Generally the same questions discussed on page 23 on detention authority also applied to recalls. They stated that recalls should be limited to products that present a significant health hazard. We believe that these concerns have merit and should be considered before taking action to establish recall authority.

We noted that such legislative proposals as the proposed Pure Food Act of 1972 include provisions which would authorize recall. The proposal states that, when the Secretary of HEW determines that a food product posses a significant potential health hazard, he may order the recall of the food product. Similarly the proposed Federal Environmental Pesticides Control Act of 1972 includes provisions for recall by EPA when the registration of a pesticide is suspended.

## CONCLUSION

Effective corrective actions to remove violative products from the market may--in addition to protecting the consumer from harmful or potentially harmful products--serve to encourage a higher degree of compliance by industry with those requirements of law designed to insure consumer protection.

However, we believe that neither seizures nor voluntary recalls provide FDA with a means of effectively removing products from the market. Seizure actions, beside being slow, are limited in scope, and recalls--being voluntary--are not enforceable by FDA.

We believe that a new regulatory measure, recall authority, is needed. This measure would combine the scope of voluntary recalls with the enforcement authority of seizures while adding an element of speed. It would also eliminate the need for initiating time-consuming and burdensome court actions for each location involving violative products. At the same time, it would provide the statutory authority needed by FDA to eliminate the delays that can plague recalls.

The House of Representatives is now considering legislative proposals, such as the proposed Pure Food Act of 1972 which, if enacted, would provide FDA with recall authority for food commodities. We believe, however, that this authority should extend to all products under FDA's responsibility.

## RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary of HEW propose legislative changes to the FD&C Act and the Federal Hazardous Substances Act to provide FDA with the authority to require firms to recall violative products for all products under FDA's responsibility.

HEW advised us that it was giving serious consideration to the inclusion of our proposal in its legislative program for the Ninety-third Congress. (See app. I.)

## RECOMMENDATION TO THE CONGRESS

To improve FDA's ability to remove violative products from the market, we recommend that the Congress consider amending the FD&C Act and the Federal Hazardous Substances Act to provide FDA with the authority to recall violative products.

DEPARTMENT OF HEALTH EDUCATION AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON D C 20201

JUL 31 1972

Mr. Morton A. Myers
Assistant Director
General Accounting Office
Washington, D. C. 20548

Dear Mr. Myers:

This is in response to your letter of June 6, 1972, requesting the Department's comments on a draft of a proposed report of the General Accounting Office entitled "Lack of Authority Limits Consumer Protection: Problems in Identifying and Removing from the Market Products Which Violate the Law."

The GAO report analyzes the authority of the Food and Drug Administration 1) to examine records needed to identify and remove from the market products known or suspected of violating the statutes administered by the Secretary through FDA, 2) to detain such products; and 3) to remove such products from the market. On the basis of this analysis, the report concludes that legislation should be enacted to provide the Department with certain additional authority.

The GAO conclusions with respect to the limitations of the analyzed statutes are legally correct, and the particular cases and other data cited by the report are confirmed by FDA's records.

We are currently giving the most serious consideration to the inclusion of GAO's legislative proposals in the Department's legislative program for the next Congress. It should be recognized, however, that any such proposals, if adopted by the Department, must be submitted for clearance to the Office of Management and Budget and must be coordinated by that office with other interested agencies within the Executive Branch. It is therefore not possible for us to anticipate the outcome of this process at this time.

Sincerely yours,

James B. Cardwell
Assistant Secretary, Comptroller

APPENDIX II

## PRINCIPAL OFFICIALS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

| | Tenure of office | |
|---|---|---|
| | From | To |
| SECRETARY OF HEALTH, EDUCATION, AND WELFARE: | | |
| Elliot L. Richardson | June 1970 | Present |
| Robert H. Finch | Jan. 1969 | June 1970 |
| Wilbur J. Cohen | Mar. 1968 | Jan. 1969 |
| John W. Gardner | Aug. 1965 | Mar. 1968 |
| ASSISTANT SECRETARY (HEALTH AND SCIENTIFIC AFFAIRS) (note a): | | |
| Merlin K. DuVal, Jr. | July 1971 | Present |
| Roger O. Egeberg | July 1969 | July 1971 |
| Philip R. Lee | Nov. 1965 | Feb. 1969 |
| COMMISSIONER, FOOD AND DRUG ADMINISTRATION: | | |
| Charles C. Edwards | Feb. 1970 | Present |
| Herbert L. Ley, Jr. | July 1968 | Dec. 1969 |
| James L. Goddard | Jan. 1966 | June 1968 |
| Winton B. Rankin (acting) | Dec. 1965 | Jan. 1966 |

[a]In March 1968 the Assistant Secretary was given direct authority over the Public Health Service and FDA, and the functions of the two organizations were realigned.

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