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REPORT TO THE CONGRESS

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Dimensions Of Insanitary Conditions In The Food Manufacturing Industry

B-164031(2)

Food and Drug Administration
Department of Health, Education, and Welfare

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BY THE COMPTROLLER GENERAL OF THE UNITED STATES

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APRIL 18, 1972

COMPTROLLER GENERAL OF THE UNITED STATES
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 on dimensions of insanitary conditions in the food manufacturing industry. Administration of activities discussed in this report is the responsibility of the Food and Drug Administration, Department of Health, Education, and Welfare.

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.

Elmer B. Staats

Comptroller General
of the United States

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Contents

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ABBREVIATIONS

FDA	Food and Drug Administration
FD&C Act	Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare

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COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

DIMENSIONS OF INSANITARY CONDITIONS
IN THE FOOD MANUFACTURING INDUSTRY
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D I G E S T

WHY THE REVIEW WAS MADE

The Food and Drug Administration (FDA) is required, by law, to provide assurance that food products shipped across State borders--which includes most of the foods purchased by the American people--are processed under sanitary conditions and are safe, pure, and wholesome to eat.

The General Accounting Office (GAO) wanted to know whether FDA was able to provide this assurance.

FDA describes the food industry in the United States as comprising some 60,000 establishments whose output results in about $110 billion in purchases by consumers each year.

FDA's inventory of establishments subject to inspection includes about 32,000 food manufacturing and processing plants. FDA inspects such plants to determine whether their products meet requirements of the Food, Drug, and Cosmetic Act (FD&C Act). FDA's inventory includes also about 28,000 establishments of other types, such as storage facilities and repacking and relabeling plants. It excludes restaurants, retail stores, and meat and poultry slaughtering and processing plants.

To assess sanitary conditions in the food manufacturing industry, GAO requested FDA to inspect 97 food manufacturing and processing plants selected at random from about 4,550 food manufacturing and processing plants in six FDA districts including 21 States. (See pp. 19 and 20.)

GAO auditors accompanied FDA inspectors on their inspections of 95 of the plants.

The 97 plants had annual sales of about $443 million. They manufactured or processed bakery products, candy, fish, flour, carbonated beverages, cheese, ice cream, fruits, vegetables, popcorn, chips, sugar, jams and jellies, macaroni, pizzas, spices, etc.

This report has two basic purposes: (1) to show the dimensions of insanitary conditions in the food manufacturing industry and (2) to suggest ways to improve the FDA's management of the program which is intended to ensure compliance by the industry with standards of sanitation required by the FD&C Act. Conditions believed to exist in the industry have been projected through the use of statistical sampling techniques. Therefore it would not be equitable to single out by name the 97 plants visited from the 4,550

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plants which formed the basis for the statistical projection. Accordingly the plants have not been identified in the report.

FINDINGS AND CONCLUSIONS

Overall findings

During the past 3 years, FDA inspections have indicated that sanitary conditions in the food industry in the United States are deteriorating. FDA did not know how extensive these insanitary conditions were and therefore could not provide the assurance of consumer protection required by the law.

A serious problem of insanitary conditions exists in the food manufacturing industry. Several actions must be taken by FDA to alleviate these conditions.

Existing conditions

Of the 97 plants included in the sample, 39, or about 40 percent, were operating under insanitary conditions. Of these, 23, or about 24 percent, were operating under serious insanitary conditions having potential for causing, or having already caused, product contamination.

Photographs of conditions at some plants, taken during FDA-GAO inspections, and detailed descriptions of some of the inspection results, will be found in chapter 2.

On the basis of the sample, GAO estimated that 1,800, or about 40 percent, of the 4,550 plants were operating under insanitary conditions, including 1,000, or about 24 percent, operating under serious insanitary conditions.

FDA officials advised GAO that conditions at plants located in the 21 States would, in their opinion, be representative of conditions at plants nationwide.

Inspection manpower

FDA has not had the money or manpower to identify promptly all the food plants operating under insanitary conditions. During the last 3 years, FDA has sharply reduced its sanitation inspection coverage of food plants in an attempt to cope with more critical problems, such as microbiological contamination and drug hazards.

FDA has a management improvement program under way to develop a system for improving the effectiveness of its field operations. (See p. 31.)

Although it has a responsibility under the FD&C Act, FDA generally does not inspect restaurants and other retail food stores but relies instead on State and local officials for this regulation. (See p. 25.)

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According to officials of the Department of Health, Education, and Welfare (HEW), the President, HEW, and FDA have recognized the need to increase and improve the inspection capability of FDA to make an effective impact upon present insanitary conditions of the food manufacturing industry.

Enforcement

In several instances of insanitary conditions found during plant inspections, GAO noted a need for more timely and aggressive enforcement action by FDA. In 14 of 111 enforcement actions reviewed, or 13 percent, the action to correct the problem was inadequate for a variety of reasons. (See p. 35.)

Although judgment is involved in selecting the appropriate actions in each case, criteria or guidelines are needed to assist the FDA districts in making these decisions, particularly for repeated violators.

Causes of conditions

Although responsibility for sanitation rests with the food manufacturers, GAO believes that factors contributing to the poor sanitation conditions in the industry are (1) FDA's limitation in resources to make inspections and (2) lack of timely and aggressive enforcement actions by FDA when poor sanitation conditions are found.

During fiscal year 1972 FDA plans to inspect about 9,400 food establishments and has 210 inspectors to do the job. The planned number of inspections clearly is inadequate to detect all insanitary establishments.

FDA's inventory of food manufacturers for planning inspections and measuring the scope of its plant inspection responsibility was not complete or accurate. For six FDA districts, 22 percent of the plants listed were out of business, 8 percent were misclassified as food manufacturers, and 6 percent were not an FDA inspection responsibility.

FDA officials told GAO that there are food plants in existence which may not be on its inventory because, in the absence of plant registration requirements, FDA does not have an effective means of identifying all food plants subject to the FD&C Act. (See p. 19.)

More effective use of consumer complaints, an accurate inventory of food plants subject to inspection, and data indicating the effectiveness of inspections and regulatory actions could contribute to improving sanitary conditions of the food manufacturing industry.

FDA should (1) notify violators officially of sanitation standards violated, (2) request a prompt reply, and (3) monitor cases to promote corrective action. Without these actions, plants may continue to disregard sanitation standards, making reinspections necessary to determine whether corrective actions have been taken. (See p. 40.)

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Providing in the law for civil penalties (fines) for violations of the FD&C Act would allow FDA more flexibility in enforcing sanitation standards. (See p. 40.)

Consumer complaints

FDA is devising a computerized system to record consumer complaints to identify industry and product problem areas. The output of the system, in GAO's opinion, should be used also to monitor the disposition of such complaints.

Insanitary products that had reached the consumers might have gone undetected by FDA for some time had not the consumer complained.

RECOMMENDATIONS OR SUGGESTIONS

GAO recommends that the Secretary, HEW, direct FDA, to:

--Periodically select and inspect a representative number of food plants to assess industrywide conditions and report its assessments to the Congress.

--Periodically evaluate the accuracy of the inventory of food plants to be inspected so that FDA will know the scope of its responsibilities and resources needed for sanitation inspections. FDA should provide this data to the Congress for the same reason.

--Establish milestones for implementing its management improvement program for using statistical techniques to identify problem areas, allocate resources, and measure the effectiveness of its regulatory actions.

--Monitor the implementation of the improvement program and advise appropriate congressional committees periodically on the progress being made in, as well as the various levels of resources needed for, implementing the program; and develop an interim plan of action, pending the completion of this program, for consideration by the Congress.

--Establish criteria for the districts to use in determining (1) when more aggressive action should be taken against plants that violate good manufacturing practice regulations and (2) what type of action should be taken.

--Take a stronger enforcement posture against those plants that show continuing flagrant disregard of the FD&C Act.

--Issue written notices in all cases of plants not complying with the FD&C Act and request written responses on actions taken or planned to correct the violations and to ensure continued compliance.

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--Obtain feedback on the disposition of all cases referred to State or other regulatory bodies for corrective action.

--Implement a uniform system for recording consumer complaints to monitor the disposition of complaints at the local level and to provide headquarters' officials with a means of identifying industry and product problems affecting more than one district.

AGENCY ACTIONS AND UNRESOLVED ISSUES

GAO submitted a draft of this report to the Secretary, HEW, for comment. The views of FDA and HEW were discussed with GAO and included in the report. HEW concurred in GAO's recommendations and advised that a number of corrective actions had been or would be taken. (See pp. 17, 22, 32, 40, and 44.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

In the light of the insanitary conditions shown to exist in the food manufacturing industry, the Congress should, upon receipt of a more accurate inventory of food plants under FDA's jurisdiction and an interim plan of action, consider the adequacy of FDA's inspectional coverage of food plants with the resources available under its current appropriation.

The Congress should also be aware that FDA relies almost entirely on State and local governments for inspectional coverage of some 500,000 restaurants and retail food stores that receive or ship products interstate. Inspections of these establishments by FDA to the extent necessary to judge whether such reliance is justified, would require the use of inspection resources.

To attain additional flexibility for enforcing the FD&C Act, the Congress should consider amending the law to provide for civil penalties when food sanitation standards are violated.

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CHAPTER 1

INTRODUCTION

The programs of the Food and Drug Administration are directed at a single overall objective--consumer protection. FDA's mission is to ensure that food is safe, pure, and wholesome; drugs and therapeutic devices are safe, effective, and properly labeled; and all products are packaged and presented honestly to the public.

The General Accounting Office, to assess the sanitary conditions of the food manufacturing industry, randomly selected 97 food manufacturing plants in six FDA districts including 21 States and requested FDA to inspect these plants accompanied by GAO personnel. (See app. I.)

This report has two basic purposes: (1) to show the dimensions of insanitary conditions in the food manufacturing industry and (2) to suggest ways to improve the FDA's management of the program which is intended to ensure compliance by the industry with standards of sanitation required by the FD&C Act. Conditions believed to exist in the industry have been projected through the use of statistical sampling techniques. Therefore it would not be equitable to single out by name the 97 plants visited from the 4,550 plants which formed the basis for the statistical projection. Accordingly the plants have not been identified in the report.

The Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301), gives FDA regulatory authority over foods that are received or shipped in interstate commerce. Under the FD&C Act, a food is considered adulterated, and therefore prohibited from interstate commerce, if, among other things, it is:

--composed, in whole or in part, of any filthy, putrid, or decomposed substance or otherwise unfit for food.

--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.

Filth includes contaminants, such as rodent urine and excreta, insects, or other objectionable materials, which would not knowingly be eaten. The FD&C Act does not authorize any tolerance for filth or decomposition in foods.

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The Secretary of Health, Education, and Welfare issued regulations (21 CFR 128, April 26, 1969) for determining whether food has been prepared, packed, or held under sanitary conditions. Some examples of good manufacturing practices cited in the regulations are:

--The design, construction and, use of equipment to preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

--Effective measures taken to exclude pests from the processing areas and to protect against contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects).

FDA describes the food industry in the United States as comprising some 60,000 establishments whose output results in about $110 billion in purchases by consumers each year.

FDA's inventory of establishments subject to inspection includes about 32,000 food manufacturing and processing plants. FDA inspects such plants to determine whether their products meet requirements of the FD&C Act. FDA's inventory (which excludes restaurants, retail stores, and meat and poultry slaughtering and processing plants) includes also about 28,000 establishments of other types, such as storage facilities, and repacking and relabeling plants.

For fiscal year 1972, FDA will devote 210 man-years to making about 9,400 inspections of food establishments to determine whether food products are in compliance with the FD&C Act. Meat and poultry plants are under the jurisdiction of the Department of Agriculture.

When adulterated products or insanitary plant conditions that may cause adulteration are found, FDA can initiate one or more of the following legal actions through the Department of Justice.

--Prosecute an individual who violates provisions of the FD&C Act.

--Enjoin a plant or individual to perform or not perform some act.

--Seize any food that is adulterated or misbranded when introduced into, or while in, interstate commerce.

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During fiscal year 1970, FDA initiated 33 prosecutions, 23 injunctions, and 267 seizures. For minor infractions, FDA can issue to the violator a written notice or warning to correct the conditions.

Although recall is not specifically provided for under the FD&C Act, FDA permits firms to voluntarily recall products alleged to be in violation of the FD&C Act. During fiscal year 1970, 355 voluntary recalls were instituted. Also it is FDA policy to issue letters on adverse findings to top management of firms when significant insanitary conditions are found. This action does not preclude the use of other legal remedies. Appendix II contains additional comments concerning FDA enforcement alternatives.

FDA is administered by a Commissioner, under the direction of the Assistant Secretary for Health and Scientific Affairs, HEW. Policies and procedures are established at FDA's headquarters, Rockville, Maryland, and the day-to-day operations are carried out by 17 district offices[1] located throughout the United States. FDA's appropriation for fiscal year 1972 was about $99.7 million.

We have issued several reports[2] to the Congress on the results of sanitation inspections by the Department of Agriculture at meat and poultry plants. This is our first report on FDA's activities in the sanitation area and the first of several reviews wherein the adequacy of resources and legislative authority will be considered in assessing FDA's ability to accomplish its mission.

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[1]The district offices are administered by 10 FDA regional offices. In December 1971 district offices were established in Puerto Rico and New Jersey, bringing the total to 19.

[2]"Enforcement of Sanitary, Facility, and Moisture Requirements at Federally Inspected Poultry Plants" (B-163450, Sept. 10, 1969); "Weak Enforcement of Federal Sanitation Standards at Meat Plants by the Consumer and Marketing Service" (B-163450, June 24, 1970); "Consumer and Marketing Service's Enforcement of Federal Sanitation Standards at Poultry Plants Continues to be Weak" (B-163450, Nov. 16, 1971).

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CHAPTER 2

ASSESSMENT OF SANITARY CONDITIONS IN FOOD MANUFACTURING INDUSTRY

We estimate that 1,800, or 40 percent, of the food manufacturing plants in 21 States were operating under insanitary conditions and that serious potential or actual food adulteration existed in 1,000 of the plants.

During the past 3 years, FDA inspections of food plants have indicated that sanitary conditions in the food industry are worsening. Because FDA selects plants to be inspected primarily on the basis of the inspection history of the plants, its inspections often were limited to the same plants. Therefore it did not know the magnitude, nationwide, of insanitary conditions in food manufacturing plants. We undertook this review in 1971 to make such a determination.

We randomly selected 97 food manufacturing plants located in six FDA districts including 21 States, and we requested FDA to inspect these plants while accompanied by GAO personnel. The 97 food manufacturing plants were selected at random from an adjusted FDA inventory of about 4,550 plants in the six districts. The inventory had been adjusted by us for plants not in operation and for other improper classifications as discussed in chapter 3 of this report. In our opinion, the FDA inspectors did a thorough job and were properly equipped. The FDA inspectors subsequently discussed the results of the inspections with plant management. The results of the inspections were classified by FDA, at our request, on the basis of the following criteria:

Significant insanitary conditions--These conditions are serious in terms of either having potential for causing product adulteration or having already caused product adulteration.

Insanitary conditions--These conditions pose a less serious potential for product adulteration.

Minor insanitary conditions--These conditions would not reasonably be considered as having a potential for adulterating the product.

In compliance--This term is self-explanatory.

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The results of the inspections are, as follows:

	Number	Percent
Significant insanitary conditions	23	23.7
Insanitary conditions	16	16.5
Minor insanitary conditions	28	28.9
In compliance	30	30.9
Total	97	100.0

The 97 selected plants, having annual sales of about $443 million, manufactured or processed bakery products, candy, fish, flour, carbonated beverages, cheese, ice cream, fruits, juices and vegetables, popcorn, chips, sugar, jams and jellies, macaroni, pizzas, spices, etc. The results of the inspections are classified by types of plants in appendix III.

Because the plants inspected were selected randomly, we believe that the conditions found would be representative of the conditions that existed in the food manufacturing plants in the six districts. Inasmuch as about 4,550 food manufacturing plants were operating in these districts at the time of our review, we estimate, at a 95-percent confidence level, that 1,800[1] plants were operating under insanitary conditions with a potential for adulterating food products and that serious potential or actual adulteration existed at 1,000[2] of the plants.

Some of the major insanitary conditions observed during the inspections were:

--Rodent excreta and urine, cockroach and other insect infestation, and nonedible materials found in, on, or around raw materials, finished products, and processing equipment.

--Improper use of pesticides in close proximity to food-processing areas.

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[1]Plus or minus 512 plants.

[2]Plus or minus 402 plants.

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--Use of insanitary equipment.

--Dirty and poorly maintained areas over and around food-processing locations.

FDA officials advised us that the conditions of plants located in the six districts would be representative of all but three of the 17 districts, nationwide, and that the conditions in the three districts would be worse.

EXAMPLES OF INSANITARY CONDITIONS

The types and extent of insanitary conditions varied among the plants inspected. The determination as to whether a plant should be classified as having significant insanitary conditions was a matter of FDA's judgment under the criteria shown on page 10. Set forth below is a description of the significant insanitary conditions found at two plants and the insanitary conditions found at a third plant. Photographs of conditions at five plants, taken during FDA-GAO inspections, are at the end of this chapter.

Plant A is a candy manufacturer that has annual sales of about $3 million and ships its product to all 50 states.

As a result of a consumer complaint of glass in the candy, a partial inspection was made by FDA at this plant 6 months before the FDA-GAO inspection. Because the inspection revealed no serious adverse conditions, the plant was classified as being in compliance. It also had been classified as in compliance on an FDA inspection made 2 months earlier.

Findings of joint FDA-GAO inspection

The more significant insanitary conditions found were:

1. Rodent- and insect-adulterated raw materials.

2. Live insects on in-process raw materials.

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3. Numerous roaches in storage and manufacturing areas.

4. Build-up of residue on equipment showing few signs of recent cleaning.

5. Moldy raw material.

6. Building in poor repair with numerous holes, cracks, peeling paint, etc.

Rodent hairs and insect fragments were found subsequently by FDA inspectors in two lots of candy after they were shipped in interstate commerce.

Corrective actions planned or taken

1. The firm destroyed 574 pounds of rodent- and insect-adulterated raw materials and finished goods and 25,000 pounds of moldy chocolate. FDA stated that it would have seized the chocolate if the firm had not agreed to destroy it.

2. The firm recalled certain lots, comprising 7,100 boxes, of candy that the FDA sample analysis showed to contain rodent hair and insect fragments. The recall was published in the national FDA monthly recall list and was publicized on the national wire services, radio, and television and in several newspapers.

3. The firm shut down all operations for about 3 weeks to correct the significant problems identified during the inspection.

4. The firm was cited and charged with shipping an adulterated product in interstate commerce and with adulterating raw materials which had been received in interstate commerce. In view of the wide publicity generated by the recall and the actions the firm was taking to correct the insanitary conditions, however, FDA advised us that they did not plan to pursue prosecution.

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Plant B is a bean cannery that has annual sales of about $3 million and ships about 70 percent of its product interstate.

FDA inspected this plant in April 1968 and found it to be in compliance. FDA files contained a report of a State inspection made 10 months before the FDA-GAO inspection which showed the plant to be in compliance. The State inspection was a follow-up to one it had made 3 months earlier which noted several adverse conditions.

Findings of joint FDA-GAO inspection

Some of the more objectionable insanitary conditions noted were:

1. Rodent-infested raw materials.

2. Moldy raw materials.

3. Numerous live roaches and flies in the manufacturing area.

4. Beans spilled on a floor area subject to foot traffic were scooped up and placed back in line for canning.

5. Can-washing equipment, through which open cans were passing, was inoperative and contained live roaches.

6. Building had numerous holes and cracks and was generally not rodent or insect proof.

Corrective actions planned or taken

1. About 5,800 pounds of rodent- and mold-contaminated beans were destroyed.

2. FDA sent a postinspection letter (see definition in app. II, p. 49) to the firm 14 days later and reinspected the plant 30 days after the inspection.

3. The firm was cited as a result of the inspection and charged with adulterating an interstate product and

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manufacturing under conditions whereby materials received in interstate commerce might become adulterated.

4. A hearing was held by FDA and no further regulatory action was taken because reinspection revealed improvement in plant conditions and a change in ownership of the firm.

Plant C is a fish cannery that has annual sales of about $3 million and ships about 30 percent of its product interstate.

The plant was inspected by FDA in November 1969 and was classified as being in compliance. FDA again inspected the plant in April 1970, and several insanitary conditions were noted.

Findings of joint FDA-GAO inspection

Insanitary conditions observed during the inspection included:

1. Fish being butchered on water-soaked wooden planks that were badly scarred and had a musty odor.

2. Ice-shaving room with flaking and peeling paint, and ice shavings containing dirt particles in contact with butchered fish.

3. Fish stored directly on the floor in an area where employees walked.

4. A push broom was used to sweep off the surface of the butchering table and then was placed on the floor.

5. Openings under warehouse doors that could allow rodent entry. A dead mouse was noted in a bait box adjacent to the doors.

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Corrective actions planned or taken

1. The insanitary conditions noted were discussed with plant management, which promised corrective action.

2. The plant was scheduled for reinspection.

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CONCLUSION

We believe that a serious problem of insanitary conditions exists in the food manufacturing industry, warranting continuous assessment and attention by FDA.

RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

For Congress and HEW to give adequate consideration to the resource needs of FDA, it is necessary to have a current assessment of industrywide sanitary conditions in food plants. Therefore we recommend that the Secretary of HEW direct the Commissioner, FDA to periodically select and inspect a representative number of food plants to assess industrywide conditions and report its assessments to the Congress.

HEW concurred in our recommendation.

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The photographs which follow were taken by FDA inspectors of conditions found during FDA-GAO inspections at five plants.

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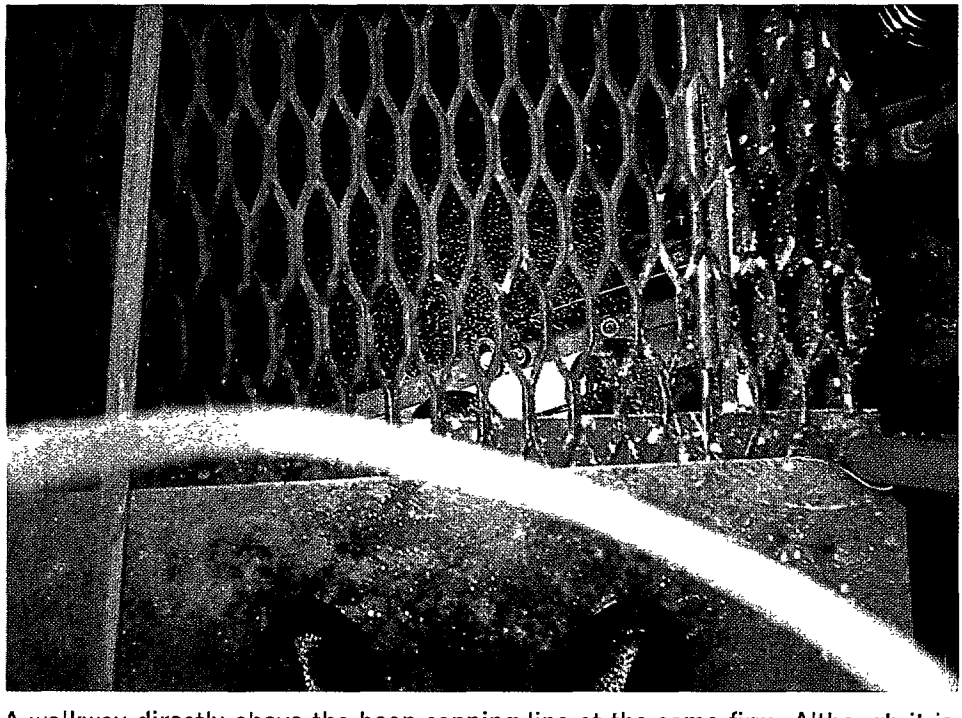
Beans spilled on a catwalk subject to foot traffic at a cannery. The beans are scooped from the floor with a shovel and are put back in line for canning.



A walkway directly above the bean-canning line at the same firm. Although it is partially covered with sheet metal, most of the walkway is open allowing foreign matter to drop into the cans as people walk on it.

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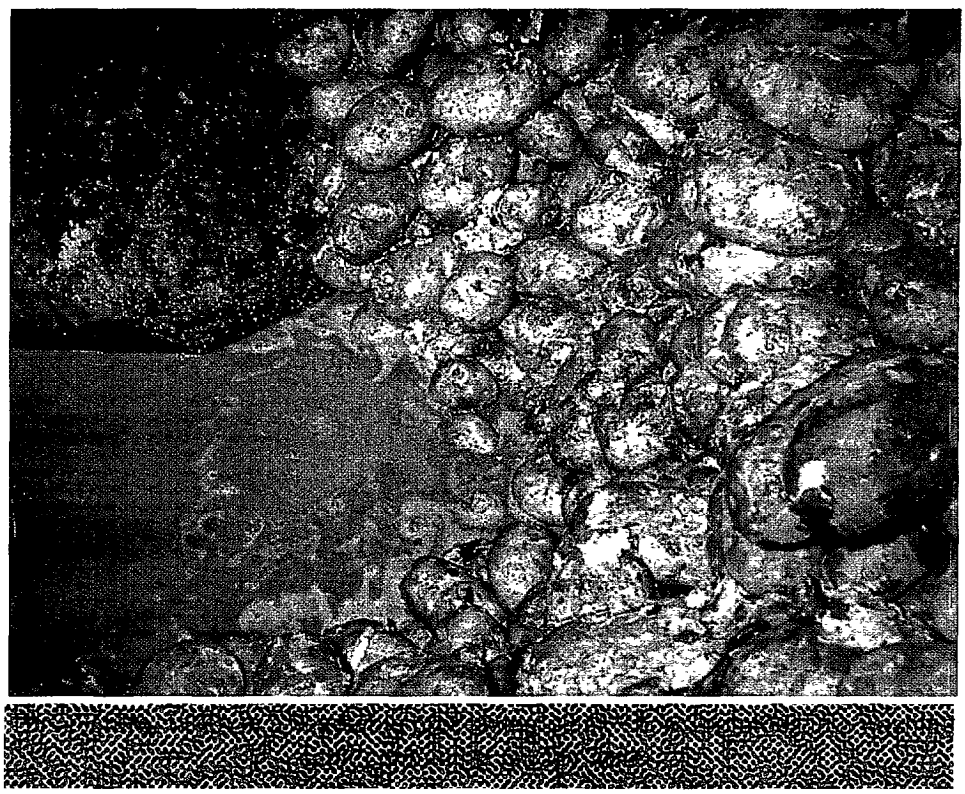
View of the back of a bakery. Note the open door, the trash, and the debris which, according to FDA, could provide rodent harborage.



Potatoes evidencing rot, which had already been screened for final processing at a vegetable-processing plant.

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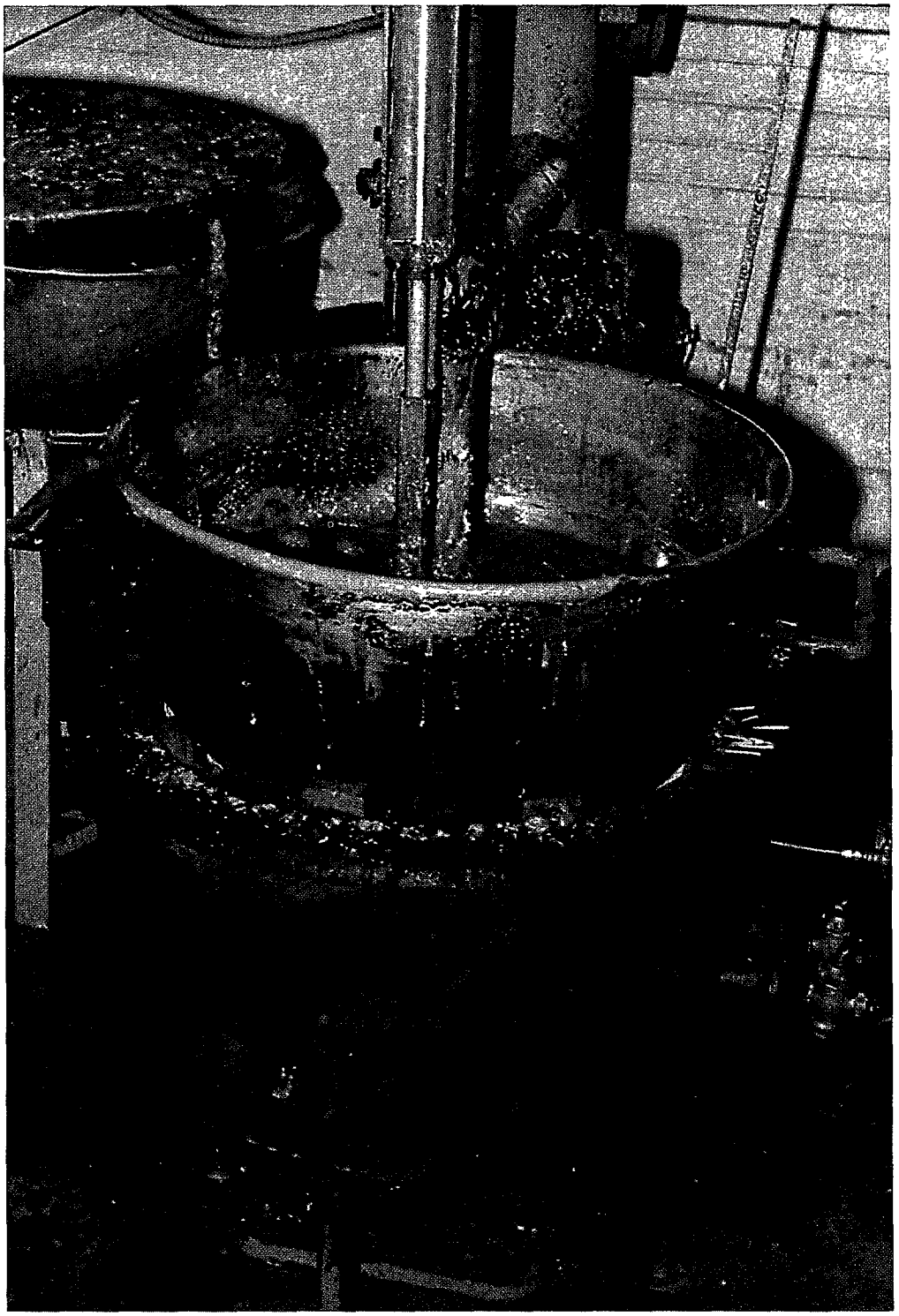

A cooking kettle evidencing charred areas, residue, encrusted material and lack of cleaning at a candy manufacturer.

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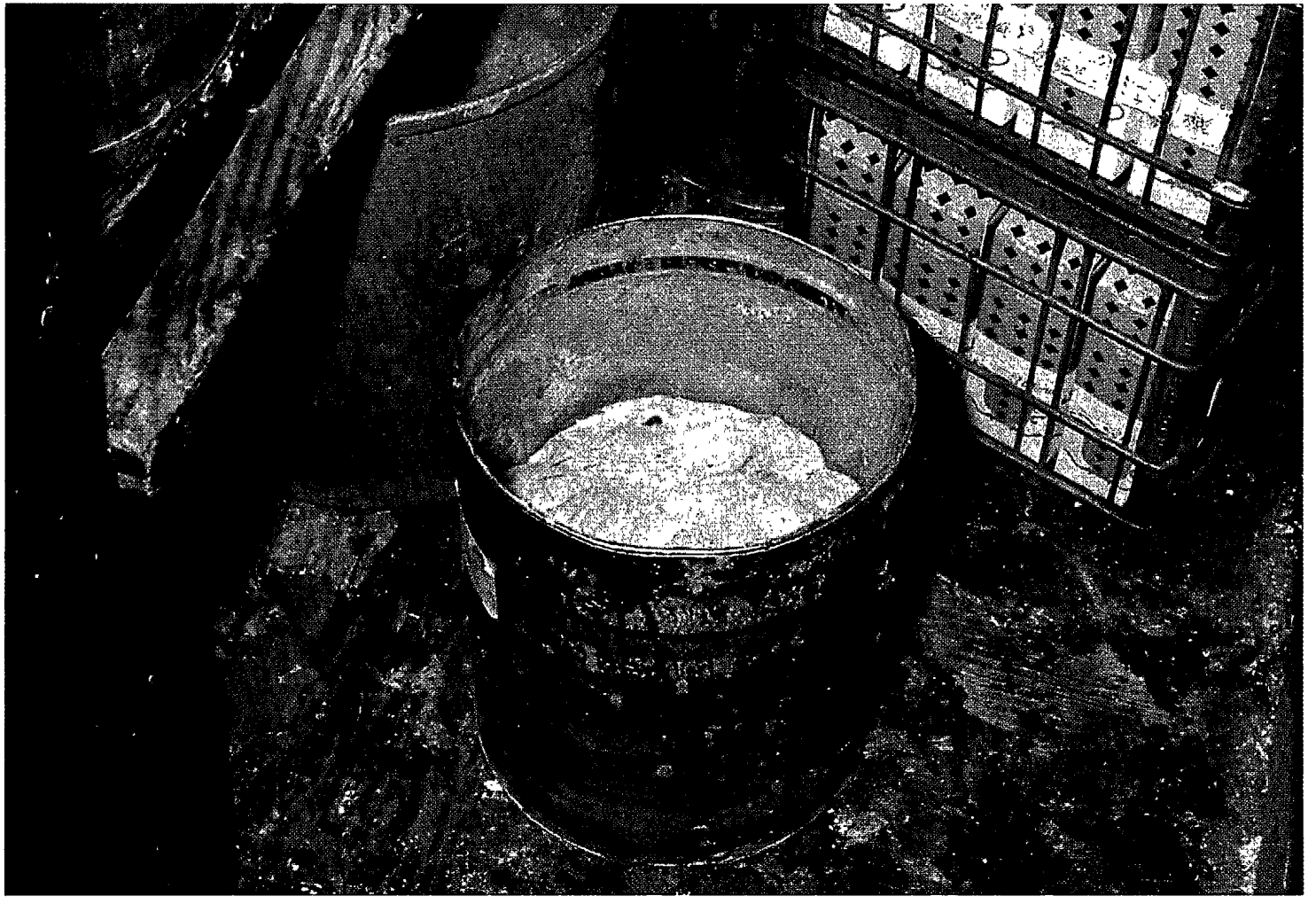

An open can containing unused raw materials. Note the extraneous material in the dough.

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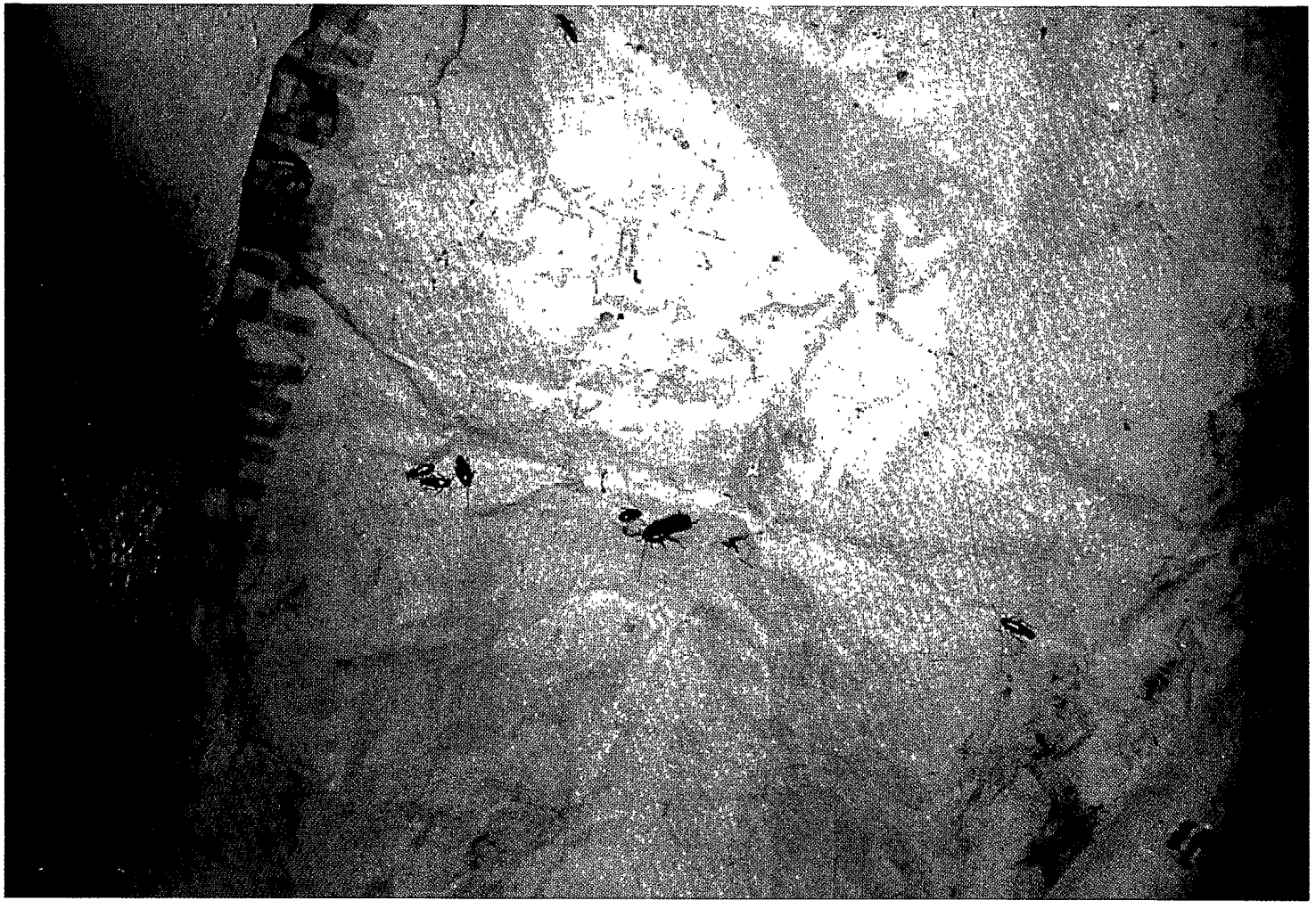

Live cockroaches found under an empty paper bag next to processing equipment. As this bag was raised so the photograph could be taken, other roaches not shown scattered.

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A rodent-gnawed bag of flour located in a raw material storage area. Rodent pellets can be seen on the bag.

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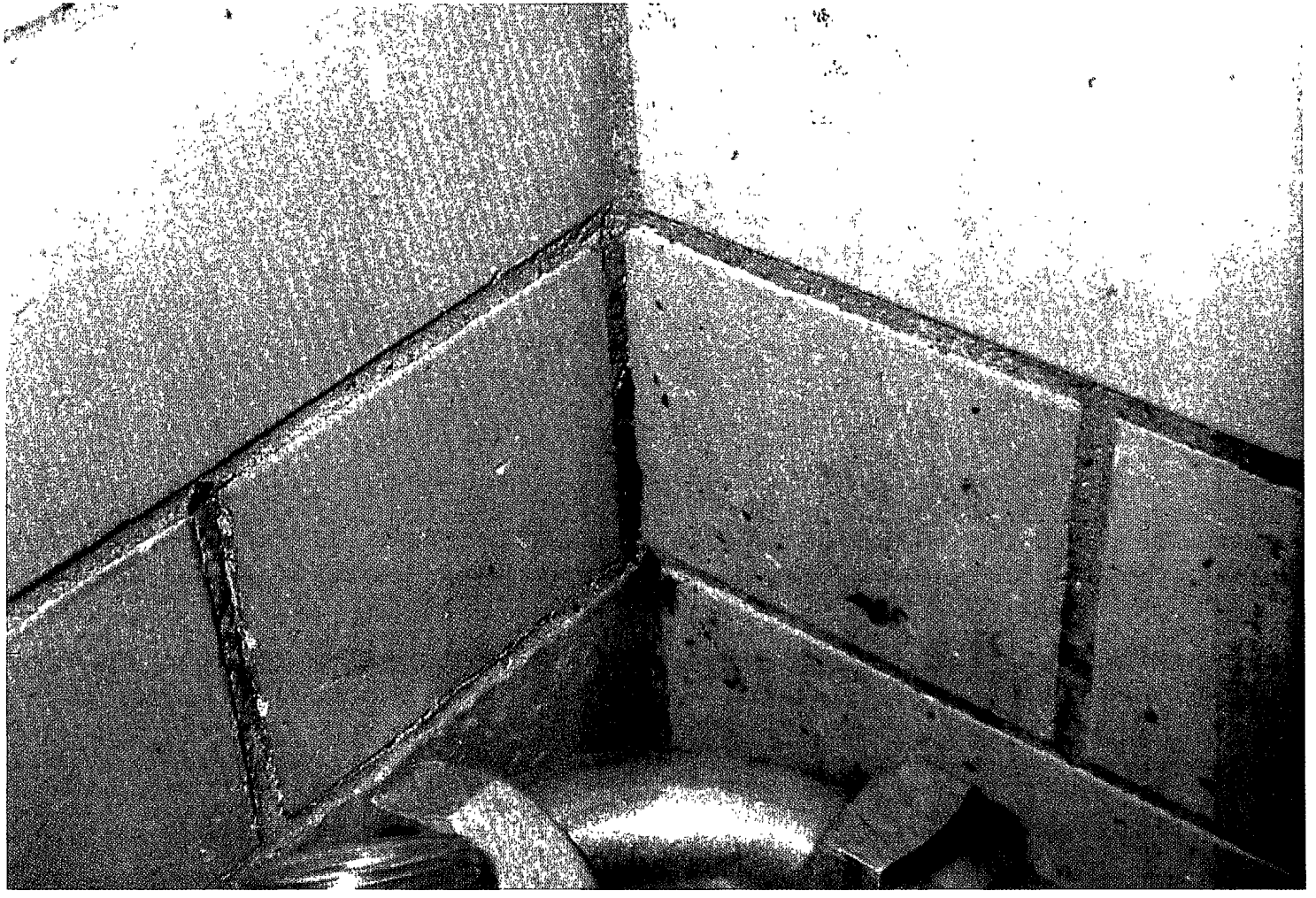

Cockroach-type insects creeping up the corner wall behind the pasteurizer and homogenizer in an ice-cream firm. Over 25 roach-type insects were noted in this area during the inspection.

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CHAPTER 3

INVENTORY OF FOOD ESTABLISHMENTS

FDA needs to determine the scope of its plant inspection responsibility to improve its basis for planning inspections of food plants. The major input used by FDA to plan its inspectional coverage of food plants is the establishment inventory--a document which lists food plants subject to regulation by FDA.

FDA requires each district to maintain a detailed inventory of plants subject to the FD&C Act. The plants are classified as manufacturing (processing), warehousing, repacking, etc. Plants that sell products directly to the consumer, such as restaurants and retail stores, although subject to the FD&C Act are generally not included in the inventory[1] as FDA relies on State and local officials to regulate this sector of the food industry. The inventory includes such data as types of products produced, annual sales volume, and results of inspections. Both the headquarters and the districts use the inventory to schedule inspections of food plants.

The inventory of food manufacturers in the six districts included in our review was not complete or accurate. About 22 percent of the plants were out of business, 8 percent were misclassified as food manufacturers, and 6 percent were not an FDA inspection responsibility. FDA officials have advised us that there are food plants in existence which may not be included on the inventory because, in the absence of plant registration requirements, FDA does not have an effective means of identifying all food plants subject to the FD&C Act.

To randomly select 97 food plants for our assessment of sanitation in the food manufacturing industry, we had to consider a sample size of almost twice that number. A summary

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[1]The 97 food manufacturing plants in our sample included six retail bakeries and one seafood store that received but did not ship products interstate.

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of the inaccuracies found in the sample and the estimated impact on the total food manufacturing plant inventory of the six districts is shown below.

	Number of plants in sample	Projected conditions in inventory of six districts	Percent of totals
Firms in original sample which could not be used:			
Out of business	52	2,099	22
Not an FDA responsibility	17	556	6
Misclassified as food manufacturer	13	764	8
	82	3,419[a]	
Plants inspected	97	4,567	47
	179	7,986	
Seasonal plants not in operation		1,158[b]	12
Manufacturers of food for nonhuman consumption		551[c]	5
Total inventory of food manufacturing plants in six districts		9,695[c]	100

[a]Based on a 95-percent confidence level, plus or minus 585 plants.

[b]Based on a 95-percent confidence level, plus or minus 411 plants.

[c]Figures according to FDA inventory.

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The inventory data indicating the dollar volume of sales of the plants in our sample was not current. Not having a reliable measure of the size of the food plants in the inventory could result in the selection of plants for which the dollar volume of sales was not representative. FDA has no legal authority to obtain this information and must rely on data volunteered by the firms or their inspectors' best estimates.

An FDA study to evaluate the feasibility of using a sample to determine the quality of a specific product, nationwide, showed that the current inventory could not be used effectively in selecting the population to be sampled. Supplemental information had to be obtained by the districts, and even this data was not always accurate.

FDA has informed the responsible subcommittee of the House and Senate Committee on Appropriation during the first session of the Ninety-second Congress that FDA resources would enable it to inspect the 60,000 or more food establishments in its inventory on the average of once every 5 to 7 years. The unreliability of the inventory listing of food plants limits the accuracy and value of the computation of the average inspection period--every 5 to 7 years--to be used in assessing FDA's resource needs by the Congress and HEW.

CURRENT EFFORTS TO IMPROVE INVENTORY

FDA has historically maintained a file of food establishments from which it has scheduled its inspectional activities. The need for an up-to-date inventory was recognized by FDA as early as 1959. FDA has advised us that, since that time, they have made several attempts to improve the inventory. At the time of our review, however, it was still inaccurate.

FDA has contracted with a private credit organization to obtain data on establishments whose products may be subject to FDA regulatory authority. The data will be reconciled with current FDA inventory records. FDA estimates that a complete and accurate inventory should be available by January 1973 and plans to contract periodically to update the inventory.

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In addition, legislative proposals, such as House bill 12478, have been introduced which, if enacted, would require food establishments distributing their products in interstate commerce to register with the Federal Government and to provide information on their locations, the products produced, etc. Such a requirement could provide FDA with a current and accurate inventory of food establishments.

FDA officials advised us that, in their opinion, such legislation was essential to their ultimately having a completely satisfactory and meaningful inventory. We agree.

CONCLUSION

FDA needs a complete and accurate inventory to (1) know which plants it is responsible for inspecting, particularly those which may not have been included in the inventory, (2) better plan its selection of plants to be inspected, and (3) provide appropriate congressional committees with meaningful statistics to relate to the need for resources to carry out the FDA mission. We believe that, even if the current efforts to improve the inventory are fully implemented, FDA periodically should verify the accuracy of the inventory. FDA could use the same selection of plants for such verification that would be required to implement our recommendation that FDA periodically assess overall sanitation in the food manufacturing industry. (See p. 17.)

RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to periodically evaluate the accuracy of the inventory so that FDA will know the scope of its responsibilities and resource requirements for sanitation inspections. FDA should provide this data to the Congress so that it may have meaningful information for assessing FDA's resource needs.

HEW concurred in our recommendation and advised us that FDA had already taken steps to improve the scope and accuracy of their inventory. HEW stated that FDA had contracted with a private credit organization to exchange their inventories of firms on a quarterly basis and that this regular and

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timely consideration of firm births and deaths should provide much more current and dependable information than was available in the past. In addition, FDA has improved its own system of recording inventory information received directly from its field offices by regular monthly updating of that information. HEW stated that it was important, however, to point out that neither by in-house effort nor by contract would the inventory be as complete, or as fully valid, as desired until and unless there was a legislative requirement that all food firms register their establishments and products with the FDA.

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CHAPTER 4

INSPECTION RESOURCES

FDA has advised several congressional committees that its inspectional resources are inadequate to inspect food establishments, on the average, more than once every 5 to 7 years.[1] This average does not include the inspecting of restaurants and retail food stores, for which FDA has an inspectional responsibility. In addition, the Congress was advised that there was no accurate measure of the impact that increased inspectional effort would have on reducing the sanitation problem.

We noted that management programs undertaken by FDA to optimize the effectiveness of its resources were long-term programs and would not have an early impact on correcting the insanitary conditions revealed in our review.

INSPECTION COVERAGE

FDA schedules its inspection coverage of food establishments through a priority system which gives greater attention to establishments considered to pose significant danger to health. For example, plants with potential problems related to bacteria and their toxins (microbiological contamination) are monitored more closely than plants classified in the lower priority categories.

Because of resource limitations, FDA has sharply reduced its sanitation inspection coverage of food establishments during the past 3 years. The decision to reduce inspection coverage was not based on a determination that traditional sanitation work was not important but, rather, on a determination that inspectional resources were needed to cope with more critical problems, such as microbiological contamination and drug hazards.

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[1] This rate is based upon FDA's current inspection resources and an inventory of about 60,000 food establishments, which is inaccurate as discussed in ch. 3.

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The following analysis of inspection coverage of food establishments by priority category shows that FDA had not inspected 32,723, or 58 percent, of the food establishments in its inventory during the 3-year period ended June 30, 1971.

Priority category	Number of establishments		
	Total	Not inspected	Percent not inspected
Microbiological contamination	13,143	5,773	44
Other food health problems (note a)	4,723	2,561	54
Sanitation	37,045	23,399	63
Economic (note b)	1,458	990	68
Total (note c)	56,369	32,723	58

[a]Establishments having potential problems with pesticides, food additives, etc.

[b]Refers to food standards and weight and labeling requirements.

[c]These statistics were obtained from FDA. See ch. 3 for comments on the need to improve the accuracy of the inventory.

This analysis does not include about 500,000 restaurants and retail food stores, which are an FDA responsibility under the FD&C Act if they receive or ship products in interstate commerce. FDA ordinarily does not inventory or plan any inspection coverage of these types of establishments but, instead, relies on State and local officials to regulate this sector of the food industry. As noted in chapter 3, our sample did include six retail bakeries and one seafood store which received but did not ship products interstate. The seven plants had annual sales of about $488,000. The joint FDA-GAO inspections showed that the six bakeries had significant insanitary conditions and the seafood store had minor insanitary conditions.

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Concerning the plants covered by the FDA-GAO inspections, we found that 70 percent of the 23 plants with significant insanitary conditions and 44 percent of the 16 plants with insanitary conditions either had not been inspected for 2 years or more or had never been inspected by FDA, as shown below.

	Never inspected	Not inspected for 2 years or more	Subtotal	Inspected within last 2 years	Total	Percent not inspected within last 2 years
Plants with significant insanitary conditions	8	8	16	7	23	70
Plants with insanitary conditions	-	7	7	9	16	44
Total	8	15	23	16	39	59

The annual sales of the 23 plants not inspected for over 2 years or not previously inspected show that the 23 plants include large, as well as small, plants.

Annual sales (millions)	Number of plants
$3 to $5	6
1 to 2.99	2
0.1 to 0.99	9
Under 0.1	6
Total	23

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STATE AGREEMENTS

To help fill the inspectional void, FDA instituted a policy in 1968 whereby the States were to provide the necessary surveillance over certain food establishments, such as bakeries, food warehouses, etc., depending upon the States' capabilities and willingness to assume the responsibility. State governments have had the authority to inspect all food establishments within their respective States, but there has been a wide variation in the extent of their authority, capability, resources, and program emphasis.

An FDA reassessment of this policy in April 1971 showed that the policy was based on assumptions that were incorrect or, at best, impractical. As a result, in June 1971 the program was revised to provide a work-sharing relationship whereby neither party would relinquish any of its statutory responsibility. The degree of work sharing depends upon the priorities, work loads, resources, and capabilities of each party.

FDA reports that it currently has formal work-sharing agreements with 26 States covering certain specified segments of the food industry. These agreements are designed to ensure that duplicative inspectional coverage is avoided and a better coordination of parallel programs is achieved. Under the revised policy the agreements are being restructured to increase the benefits of work sharing, which include savings in time and manpower due to increased efficiency, elimination of duplication, and improved application of available compliance tools. In some cases gaps in coverage have been identified and appropriate adjustments made.

When announcing the revised program, however, the Commissioner indicated that all the State and Federal resources available would be inadequate to meet the growing responsibilities for monitoring food-related activities.

PLANNED INSPECTION COVERAGE

Unforeseen problems have reduced planned inspectional coverage in the past, and such problems could affect planned inspectional coverage in the future. FDA estimates that the recent problem of identifying botulin in canned soup will

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reduce fiscal year 1972 food establishment inspections by 2,300. Inspections of many food plants were actually suspended for this reason during fiscal year 1972 because inspectors were needed to locate and remove botulin-contaminated products from the market. A comparable situation arose in fiscal year 1971 when the problems of mercury in tuna fish and microbiological contamination of drugs resulted in an estimated reduction of 2,800 food and drug inspections.

FDA plans to inspect about 9,400 food establishments in fiscal year 1972. The planned number of inspections is clearly inadequate to detect all insanitary establishments, considering (1) our estimate that 1,800 food manufacturing plants in the six FDA districts reviewed had insanitary conditions (2) the fact that the location of these plants is unknown, and (3) FDA's opinion that conditions at plants located in the six districts would be representative of conditions at plants, nationwide.

FDA's planned inspection coverage in fiscal year 1972 is based on the utilization of 210 inspector man-years to inspect domestic food establishments. We estimate that, even if FDA were to allocate all its available inspector man-years for this purpose--including those currently devoted to drugs, product safety, and imports--FDA would be able to inspect food establishments in its inventory only once every 1.7 years.

FDA AND HEW ASSESSMENT OF ADEQUACY OF INSPECTION COVERAGE

FDA district officials have stated that sanitary conditions have worsened in recent years, and it was the consensus of officials in the six districts covered by our review that present resources and frequency of inspections are inadequate to cope with the problem.

The districts had different opinions on what constituted adequate inspection frequency. One district believed that all plants should be inspected once every 2 years; three believed that an annual inspection was the desired goal for plants with potential sanitation problems and that some of the plants should be inspected more or less frequently, depending on the conditions found; and another believed that semiannual inspections were desirable. One district believed that plants should be inspected more frequently but did not specify a time interval.

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According to district officials, sanitary conditions usually worsen whenever plants are not inspected for 2 or 3 years and their experience indicates that insanitation is a continuing problem which tends to creep back into plants unless positive pressure is maintained on the industry.

In September 1971 the FDA Commissioner advised the Chairman, Subcommittee on Public Health and Environment, House Committee on Interstate and Foreign Commerce, that, to improve its food inspection capability, FDA needed, among other things, to undertake regular and more frequent inspections and to have the extra capability to react promptly to unforeseen crises. During this testimony and earlier testimony provided in August 1971, the Commissioner indicated that he would furnish the Subcommittee with information about FDA resource needs for its food activities.

In November 1971 the Secretary, HEW, forwarded to the Subcommittee a hypothetical level of increased inspection coverage which would require 3,403 additional employees and cost about $94.7 million above FDA's fiscal year 1971 food program. The increased program, among other things, would provide for annual inspection by FDA of 40,000 food establishments and for the analysis of 85,000 products collected from retail shelves. The program also would provide for 1,549 inspectors, which is about a sevenfold increase over the man-years planned for inspection of food establishments in fiscal year 1972.

The Secretary advised the Subcommittee Chairman that the proposal did not represent an FDA, HEW, or Administration commitment to seek appropriations for, or to fund, this program at the indicated levels, primarily because there was no accurate measure of the extent to which the risk of contamination could be reduced if the projected increase in the level of inspections were implemented. HEW officials advised us that the need to dramatically increase the resources available to FDA to make an effective impact upon the insanitary conditions of the food manufacturing industry had been recognized by the President, HEW, and FDA.

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FDA EFFORTS TO MEASURE AND IMPROVE EFFECTIVENESS OF OPERATIONS

Our review showed that FDA had been aware of its need for data to justify additional staff and for planning and controlling its operations since at least 1959. A consultant's study of FDA's field operations at that time showed that there was a need to:

--Establish objectives for levels of compliance by industries and by geographic areas to enable FDA to achieve more uniform protection for consumers throughout the nation.

--Determine the frequency of inspections necessary to achieve compliance objectives.

In 1966 FDA contracted with another consulting firm for a detailed review of FDA operations. The principal objective of the study was to develop an improved management system for continuous planning control and evaluation of FDA's field operations.

Following is a summary of the major recommendations of the study concluded in 1968, which were directed at problems recognized as early as 1959 that continued to exist at the conclusion of our review.

1. Develop effective product-sampling plans to maximize the chance that all manufacturers are adequately sampled.

2. Develop a list of observable conditions (key indicators) during inspections to

   a. find out which observable conditions are the best predictors of product condition,

   b. use for estimating the probability of product defect of an industry, and

   c. use for classifying an establishment in terms of its tendency toward producing defective products.

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3. Measure the effect of FDA actions on consumer protection through the "measure-act-measure" concept. This program is an attempt to assess the impact that alternative FDA actions have on improving industry conditions such as making plant inspections, issuing warning letters, or sponsoring industry training workshops.

These recommendations have been included in an overall FDA management improvement program called Project IDEA, which also considers other means of improving the effectiveness of field operations.

Our review of this management improvement program indicates that it will involve substantial data gathering, refinements, revisions, frequent evaluations, and, more importantly, a long period for full implementation. An FDA official advised us that a plan for full implementation of this program had not yet been developed and confirmed our view that implementation would be a long-term project.

As of December 1971, one food product had been sampled and analyzed; key indicators had been developed for two products and another was in process; and two studies were under way and a third was completed, to measure alternative acts in three segments of the food industry, i.e., the effectiveness of using citations, postinspection letters, and industry training workshops at candy plants, dry-storage warehouses, and grain elevators.

CONCLUSIONS

FDA's inspectional resources are inadequate to promptly identify all establishments operating under insanitary conditions, and FDA does not know what impact an increased inspectional effort would have on reducing the sanitation problem.

FDA is attempting to maximize the use of State resources, but this program is not likely to have an immediate impact on the insanitary conditions shown in this report.

FDA does have a management improvement program under way to develop a system to (1) identify with more confidence food establishments that require intensified regulatory

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efforts and those that require only spot checks, (2) identify and focus on key indicators of product quality in various types of establishments, and (3) measure the effectiveness of using specific regulatory actions. We believe that precise resource requirements cannot be established by FDA until such a management system is implemented.

In view of the insanitary conditions that exist in the food manufacturing industry, we believe that the studies by FDA that are under way should be completed as soon as possible. Additional resources would be necessary to achieve significant improvement in sanitation more promptly.

RECOMMENDATIONS TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to:

--Establish milestones for implementing its management improvement program and for using statistical techniques to identify problem areas, allocate resources, and measure the effectiveness of its regulatory actions.

--Monitor the implementation of this program and periodically advise appropriate congressional committees on the progress being made in, as well as the various levels of resources needed for, implementing the program and develop an interim plan of action, pending the completion of this program, for consideration by the Congress.

HEW concurred in our recommendations and advised us that it planned to undertake an interim plan of action which would have impact upon the insanitary conditions of the food manufacturing industry. HEW stated that this plan was reflected in the Budget of the United States for fiscal year 1973 which proposed a major increase in dollar and manpower resources for FDA to expand its food inspection program.

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MATTERS FOR CONSIDERATION BY THE CONGRESS

In the light of the insanitary conditions that exist in the food manufacturing industry, the Congress, upon receipt of a more accurate inventory of food plants under FDA's jurisdiction and the interim plan of action, should consider the adequacy of FDA's inspectional coverage of food manufacturing plants, with the resources available under its current appropriation.

The Congress should also be aware that FDA relies almost entirely on State and local governments for inspectional coverage of some 500,000 restaurants and retail food stores that receive or ship products interstate. Inspections of these establishments by FDA to the extent necessary to judge whether such reliance is justified would require the use of inspection resources.

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CHAPTER 5

FOLLOW-UP ACTIONS

FDA follow-up actions to food plant inspections should be improved to ensure that insanitary conditions are promptly corrected. Our review showed a need for more timely and aggressive enforcement actions by FDA to effect corrections of insanitary conditions without the use of scarce resources to reinspect plants in an attempt to correct insanitary conditions.

Under section 402(a)(4) of the FD&C Act a food is deemed to be adulterated if it is prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or may have been rendered injurious to health.

When adulterated products or insanitary plant conditions which may cause adulteration are found, FDA, depending upon the seriousness of the conditions, can schedule the plants for reinspection; can issue the plants postinspection letters (either warnings or adverse findings letters); or can initiate regulatory actions to seize the products, enjoin the plants to perform or not perform some acts, or cite and prosecute the responsible persons.

The criminal penalties for convicted violators are not more than 1 year in prison or $1,000 fine or both for the first offense and not more than 3 years or $10,000 or both for second and subsequent convictions for each separate charge.

In some cases, violative plants are referred to State and local officials for corrective action. The follow-up action taken by FDA depends on the seriousness of the insanitary condition, the availability of resources, and the likelihood of voluntary corrective action.

To review FDA follow-up actions, we randomly selected 72 plants that had been inspected by FDA during the period July through December 1970 and had been classified as being out of compliance with the FD&C Act. We selected also 39 plants which had insanitary conditions noted during inspections performed as part of our review.

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In our opinion, enforcement actions were inadequate in 14, about 13 percent, of the 111 plants inspected, for one or more of the following reasons.

1. Five plants that historically had shown a disregard for compliance with the FD&C Act were continually reinspected rather than subjected to more aggressive enforcement action, such as product seizure or citation of responsible individuals with the intent to prosecute.

2. Six plants were not issued postinspection letters, and, in the remaining eight cases where letters were issued, replies were not requested in seven cases because FDA policy did not require it.

3. Four problem plants were not promptly reinspected. Scheduled reinspections were from 5 to 14 months overdue.

4. Four plants were referred to State officials for follow-up action, and FDA was unaware of the corrective action taken by the plants or States. At the time of our review, 6 to 16 months after the FDA inspections, the States had not reinspected three of these plants. The fourth plant was not reinspected for 9 months.

5. Three plants were processing potentially adulterated products, and no action was taken to prevent shipment of the product in interstate commerce.

Examples of inadequate enforcement measures for two plants are described below:

Plant D is a macaroni and noodle manufacturing plant that has annual sales of about $600,000 and ships about 30 percent of its product in interstate commerce.

As summarized below, FDA made eight inspections of this plant during the 46-month period ended October 1971. Seven inspections revealed insect activity, one of which resulted in the plant's voluntarily destroying 14,352 pounds of insect-infested spaghetti. The other inspection revealed minor rodent activity.

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Date	Conditions found	Follow-up action
Dec. 1967	Limited insect activity in regrind sifter and drying equipment.	Reinspect in August 1968.
Aug. 1968	Insect activity throughout plant and in much of the equipment. Limited rodent evidence found. Firm voluntarily destroyed 14,352 pounds of insect-infested spaghetti. Careless use of insecticide. Factory samples showed rodent and insect filth although a sample of the product that was shipped interstate was not contaminated.	Reinspect in December 1968.
Jan. 1969	A number of improvements made. No insect activity. Minor rodent evidence which may have been there since the previous inspection.	Reinspect in August 1969.
Sept. 1969	Limited insect activity in the flour-handling equipment. Inadequate design and cleaning of equipment. Several small paint chips found in flour tanks. Samples collected for salmonella were negative. Residues of insecticides were found in egg noodle sample.	Reinspect in April 1970. Postinspection letter issued and reply received.
Apr. 1970	Active insect population in static material throughout plant equipment (dryers). No product or raw material contamination could be established during the inspection. However, residues of	Reinspect in September 1970.

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Date	Conditions found	Follow-up action
	insecticides and fragments of insects and a rodent hair were found in a sample of the product shipped interstate.	
July 1970	Some limited live and dead insect activity in the plant. No pesticide residues were found in sample.	Reinspect in June 1971.
May 1971	Regrind sifter contained live adult beetles and larvae which could enter the direct flow of flour to the mixing machines. Factory sample contaminated. A sample of the product shipped interstate was not contaminated.	Reinspect in September 1971.
Oct. 1971	Insect activity found in equipment. A sample of the product shipped interstate contained beetle and rodent hair fragments.	Reinspect in May 1972.

All but one of the eight inspections revealed some degree of insect activity. The May 1971 inspection disclosed live adult beetles and larvae in the manufacturing equipment which could directly contaminate raw materials, and an analysis of a sample collected at the plant showed contamination. FDA officials advised us that regulatory action was not taken against this firm because evidence of contamination was not found in the sample collected after shipment in interstate commerce.

The most recent inspection of this plant in October 1971 again showed insect activity in processing equipment, which could cause contamination. A sample collected after shipment in interstate commerce showed beetle fragments and rodent hair fragments. Another sample collected in November 1971 as a follow-up to a consumer complaint alleging live insects

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in several products disclosed numerous dark-colored specks that may have been insects or other foreign materials. A laboratory analysis showed that some sort of contamination was occurring during the manufacturing process.

An FDA official advised us that, in his opinion, this plant had been a borderline case and that inspectional evidence obtained had not been strong enough to sustain regulatory action under section 402(a)(4) of the FD&C Act, i.e., processing food under insanitary conditions whereby it may have been contaminated with filth. He further stated that regulatory action would have been taken had the samples collected after shipment shown contamination that could be related to the inspectional findings.

Headquarters' officials advised us that there were no specific criteria setting forth the conditions under which more aggressive regulatory action should be taken and that a need existed for such criteria. In our opinion, when a plant has repeatedly violated the sanitation standards of the good manufacturing practices regulation, FDA should use one of the more aggressive enforcement alternatives available to it rather than continue to reinspect the plant.

Plant E is a manufacturer of food specialty items that has annual sales of about $700,000.

An August 1970 inspection showed swollen cans of chili paste and pickled peppers, live moths and other insects in products, and mold on the outside and inside of a 100-pound bag of rice. The plant planned to return the swollen cans to its supplier, destroyed four lots of insect-infested products, and returned the moldy rice to the supplier who destroyed it.

FDA did not send a postinspection letter reporting these insanitary conditions to top management for corrective action. Without such a letter and a reply from the firm, FDA had no knowledge of whether the firm had corrected its insect problem or had returned or destroyed the swollen cans. A reinspection scheduled for May 1971 had not been made as of January 1972. FDA officials advised us that the scheduled reinspection was not made due to the low priority assigned to this case.

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FDA headquarters' officials have advised us that, by not issuing postinspection letters and receiving written response, FDA does not have any feedback on the effectiveness of its plant inspections without making reinspections.

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CONCLUSIONS

FDA has several enforcement alternatives available when violations of sanitation standards are found during plant inspections. Although judgment is involved in selecting the appropriate actions in each case, criteria or guidelines should be established to assist the districts in making these decisions.

We believe that FDA should notify violators officially of sanitation standards violated, request a prompt reply, and monitor the case to ensure prompt corrective action. Without such actions, it is necessary to make reinspections to determine whether corrective actions have been taken and, in some instances, failure to take action may contribute to a plant's continued disregard of sanitation standards.

We believe that more aggressive regulatory action should be instituted when the reinspection of a plant historically shows a disregard for the sanitation standards of the good manufacturing practices regulation. Enforcement alternatives provided under law include criminal penalties, injunctions, and letters of warning. In our opinion, the difference between the rather severe consequence of criminal penalties or injunctions, which FDA states that it is reluctant to initiate, and the relatively inconsequential letter of warning indicates that intermediate enforcement powers may be desirable to provide an effective means to obtain timely corrective action.

For instance, providing in the law for civil penalties (fines) for violations of the FD&C Act, in our opinion, would allow FDA more flexibility in enforcing sanitation standards.

RECOMMENDATIONS TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to:

--Establish criteria for the districts to use in determining when more aggressive action should be taken against plants that violate good manufacturing practice regulations and the type of action to be taken.

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--Take a stronger enforcement posture against those plants that show historical and flagrant disregard of the FD&C Act.

--Issue written notices in all cases of plants' not complying with the FD&C Act and request written responses on actions taken or planned to correct the violations and to ensure continued compliance.

--Obtain feedback on the disposition of all cases referred to State or other regulatory bodies for corrective action.

HEW concurred in our recommendations and advised us that criteria to determine when more aggressive action was to be used against violators of sanitation standards of the good manufacturing practices regulation were under development by FDA.

HEW advised us that FDA must continue to balance carefully the cost-to-benefit ratio in the expenditure of its resources to attain the greatest improvement in industry conditions. A decision on the part of FDA to pursue a course of action through the courts does not automatically end its involvement in that case. The costs to FDA in supporting actions of the Department of Justice frequently far exceed those necessary to follow some alternative course of action and, therefore, become an important factor in their decision-making process.

HEW advised us that FDA was reluctant to initiate legal actions when unsatisfactory plant conditions were not corroborated by examination of the plant's finished products. HEW stated that this reluctance was due not only to the cost consideration but also to FDA's interpretation of the results of judicial actions in this area. Also, HEW said that, because such insanitary plant conditions could not be ignored, reinspection had been used to promote voluntary correction by industry management. HEW said that, with respect to our recommendation for a stronger enforcement posture, it was reviewing its policies in this regard.

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MATTERS FOR CONSIDERATION BY THE CONGRESS

To attain additional flexibility for enforcing the FD&C Act, the Congress should consider amending the law to provide for civil penalties when food sanitation standards are violated.

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CHAPTER 6

CONSUMER COMPLAINTS

FDA district offices need a uniform system for recording the receipt and disposition of consumer complaints. The system should provide a means of monitoring corrective actions taken on a local basis and should provide for the collection of data to allow headquarters' officials to identify industry and product problems affecting more than one district.

Several district offices have reported an increase in recent years in both the number of consumer complaints and in the number of insanitary plants and adulterated products identified during inspections made as a result of complaints. Our review showed that insanitary products were reaching the consumer and would have gone undetected by FDA for some time had not the consumer complained. This situation is illustrated below.

--After receipt of three consumer complaints, including the alleged presence of foreign material in the firm's candy and illness after eating the candy, FDA inspected the plant in April 1971 and found rodent-contaminated nuts. Laboratory analysis of candy samples collected during the inspection revealed rodent hairs, urine, and metal fragments. About 30,000 pounds of nuts and 37,000 pounds of candy were destroyed as a result of this inspection. The plant was previously inspected in November 1969 and was scheduled for reinspection in November 1970. Due to higher priority work, however, the scheduled reinspection was not accomplished, and it was not until after the receipt of the three complaints in December 1970 and February and March 1971 that the plant was reinspected.

Five of the six districts had no formal system for recording the receipt and disposition of consumer complaints and did not maintain summary records of consumer complaints. As a result, there was no record of the volume of consumer complaints received by districts or of whether the complaints

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had been investigated. This situation is particularly distressing considering the fact that the overall mission of FDA is consumer protection.

Also procedures varied among districts as to whether complaints warranted follow-ups. In one district, if the reviewing official considered the complaint unwarranted, it was ignored and no record of its receipt was made.

In another district some consumer complaints referred by FDA to a local county agency for action were not monitored to ensure adequate disposition of the complaints. County officials advised us that they had no record of receiving these complaints. We found that there was no control to monitor the disposition of complaints deferred for follow-up during future inspections.

An FDA survey in August 1971 showed that consumer complaints were handled differently from district to district and that only three of 17 districts were using a system whereby consumer complaint information was retrievable. As a result, summary information relating to the number, nature, and frequency of consumer complaints on a particular firm or product was not available to FDA.

FDA is devising a computerized system which will record consumer complaint data to identify industry and product problem areas. The output of the system, in our opinion, should be used also to monitor the disposition of complaints.

RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to implement a uniform system for recording consumer complaints, which should be used to monitor the disposition of complaints at the local level and to provide headquarter's officials with a means of identifying industry and product problems affecting more than one district.

HEW concurred in our recommendation and advised us that FDA was developing a uniform system for monitoring the disposition of complaints and for providing industry and product problem trends on a national basis.

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CHAPTER 7

SCOPE OF REVIEW

We accompanied FDA inspectors on the inspection of 95 of 97 randomly selected food manufacturing plants subject to the regulatory authority of FDA. The inspections were made in six FDA districts, which included 21 States, during the period May through August 1971.

We reviewed records and interviewed agency officials at FDA headquarters and at six district offices--Boston, Dallas, Kansas City, Los Angeles, New Orleans, and Seattle. Pertinent policies, procedures and practices were examined, as were the laws and regulations governing food sanitation practices.

We also reviewed independent consultant studies of FDA field activities and contacted a number of State agencies responsible for food inspection activities.

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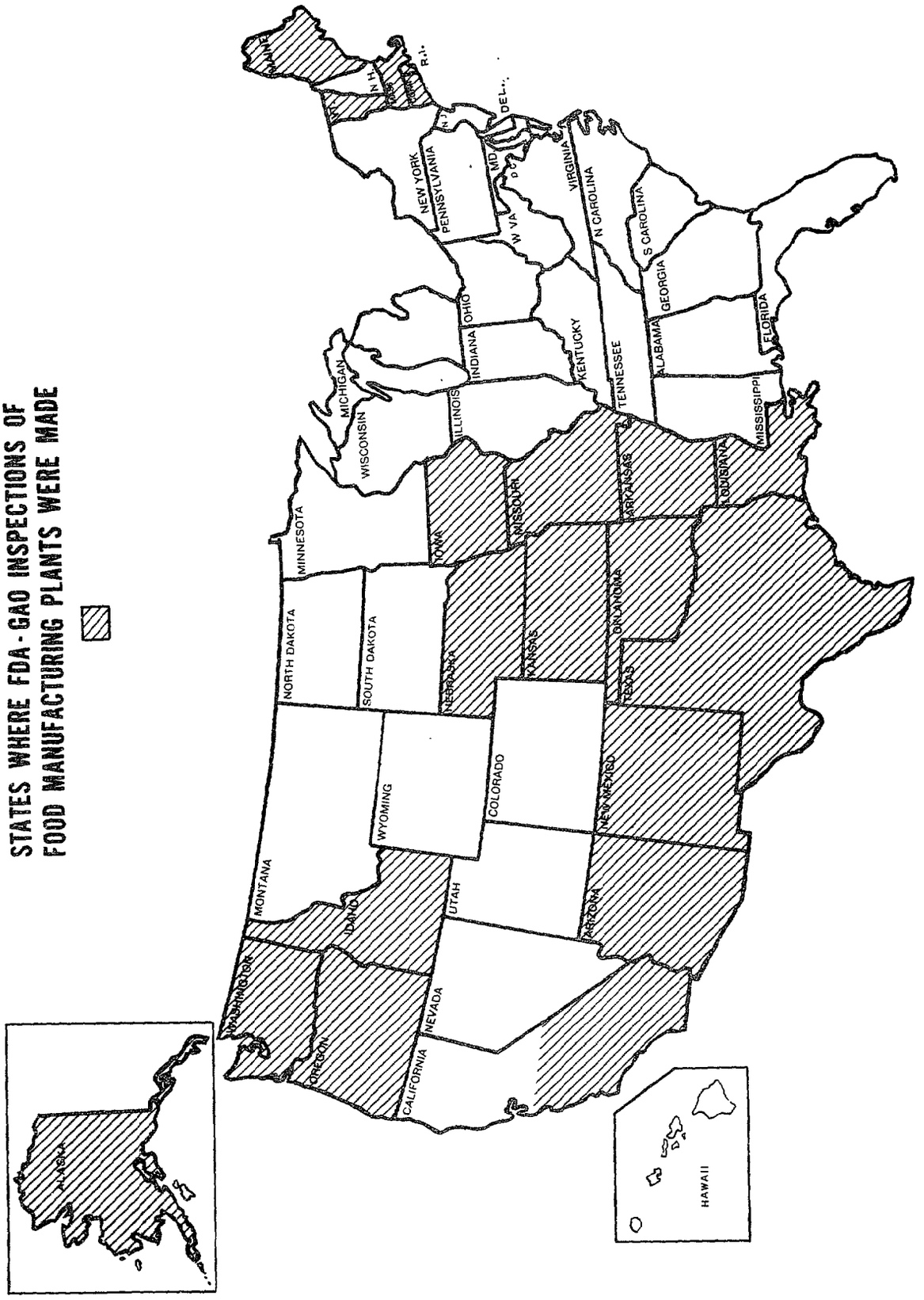

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APPENDIX II

ENFORCEMENT ALTERNATIVES AVAILABLE TO THE FOOD AND DRUG ADMINISTRATION

CRIMINAL PENALTIES

Section 301 of the FD&C Act sets forth those actions which are prohibited under the law. Section 303 provides that any person who violates a provision of section 301 be imprisoned for not more than 1 year or fined not more than $1,000, or both. For second and subsequent convictions, the imprisonment and fine are increased to no more than 3 years or $10,000, or both.

The penalties have not been revised since the FD&C Act was passed in 1938. To keep pace with changes in the value of the dollar, FDA submitted a legislative proposal to HEW for fiscal year 1972 that would increase the fine to $5,000 for first violations and $25,000 for second violations.

Citation

Section 305 of the FD&C Act provides that, before any violation of the FD&C Act is reported for institution of a criminal proceeding, the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding. To comply with this provision a Notice of Hearing, often referred to as a citation, is mailed to the alleged violator(s) and a date for response designated.

INJUNCTION

Section 302 of the FD&C Act provides for injunction against violations of Section 301. An injunction enjoins the firm or individual from performing or not performing some act.

SEIZURE

Section 304 of the FD&C Act provides that seizure proceedings may be initiated against any food, drug, device,

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or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce.

POSTINSPECTION LETTERS

Warning letter

Section 306 of the FD&C Act, under the caption "Report of Minor Violations" states that:

> "Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning."

Adverse findings letter

In 1968 FDA headquarters instructed its district offices to furnish a report to a firm whenever significant adverse conditions were observed during an inspection, regardless of whether regulatory action was contemplated. The letter is not considered to be a section 306 warning letter, and a firm generally is not asked for a reply.

Recall

A recall is described as voluntary action by a firm to remove from the market those products that present a threat to the safety or well-being of the consumer. Although such action is not provided for in the FD&C Act, FDA policy statements indicate that, over the years, recalls have been the most effective method of removing from the marketplace all units of products found to be in violation of section 301 of the FD&C Act.

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ANALYSIS OF 97 FOOD PLANTS INSPECTED BY FDA-GAO

Description of products (note a)	Total plants	Out of Compliance: Significant insanitary conditions	Out of Compliance: Insanitary conditions	Out of Compliance: Minor insanitary conditions	In compliance
Bakery products	23	10	2	5	6
Carbonated beverages and waters	17	1	3	4	9
Fish and fish products	11	2	3	6	-
Cheese, ice cream, eggs, and related products	11	3	2	3	3
Specialty items and prepared foods--chips, popcorn, cheese pizzas, prepared sandwiches, tortillas, and taco shells	8	-	2	5	1
Candy, sugar, molasses, and honey	6	1	1	1	3
Processed vegetables, potatoes, beans, pickles, vegetable salads	5	1	1	-	3
Food extracts, flavors, sauces, spices, teas, and dressings	6	1	1	1	3
Flour, macaroni, and noodle products	5	2	1	1	1
Canned fruits and juices	3	1	-	1	1
Jams, jellies, nuts, and nut products	2	1	-	1	-
Total	97	23	16	28	30
Approximate annual sales (note b) (total in millions)	$443	$43	$43	$91	$266

[a]Each plant manufactures at least one of the indicated products.

[b]Annual dollar volume of sales of plants inspected ranged from $1,500 to $85,000,000.

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PRINCIPAL OFFICIALS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE RESPONSIBLE FOR ADMINISTRATION OF 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

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

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Copies of this report are available from the U. S. General Accounting Office, Room 6417, 441 G Street, N W., Washington, D.C., 20548.

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