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HUMAN RESOURCES
DIVISION

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The Honorable John D. Dingell, Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

Subject: Evaluation of Selected Aspects of FDA's Food Manufacturing Sanitation Inspection Efforts (GAO/HRD-84-65)

This letter is in response to the Subcommittee's request that we follow up on certain issues regarding the Food and Drug Administration's (FDA's) food sanitation program which we addressed in our April 1972[1] and April 1978[2] reports. In accordance with agreements reached with your office, we developed information on the status of sanitation conditions in the food manufacturing industry and FDA's management of its inspection activities. In addition, we reviewed FDA's enforceability of Good Manufacturing Practice (GMP) regulations for assuring that foods are manufactured under sanitary conditions.

Our review showed that

—93 percent of the food manufacturers sampled nationwide had sanitary conditions that would likely prevent products from becoming contaminated;

—over half of the manufacturers included in our sample had interstate sales of 10 percent or less and therefore may more appropriately be subject to routine inspections by state and/or local governments; and

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[1]Dimensions of Insanitary Conditions in the Food Manufacturing Industry (B-164031(2), Apr. 18, 1972).

[2]Letter to the Commissioner, Food and Drug Administration, April 11, 1978.

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--GMPs, aimed at assuring that establishments operate under sanitary conditions, are valid and substantive regulations and are enforceable when a departure from GMPs represents insanitary conditions sufficient to meet the definition of adulterated food defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA is the primary federal regulatory agency charged with the safety and quality of this nation's food supply. If the food (except for meat and poultry products which are regulated by the U.S. Department of Agriculture) is involved in interstate commerce, it is under FDA's jurisdiction. Also, each state has its own statutes, regulations, and institutions concerned with the quality of food products and has the authority to inspect all food establishments within state boundaries. FDA contracts with state agencies to conduct inspections of certain establishments and provides training and technical assistance to state and local governments.

FDA derives its authority over industry food sanitation practices from the FD&C Act of 1938, as amended (21 U.S.C. 301). The act prohibits the receipt or shipment of food across state borders if it is adulterated with filthy, putrid, or decomposed substances. Through the issuance of GMP regulations FDA has outlined criteria for food establishments to follow to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions. The GMP regulations which were originally established in 1969 provide guidance on proper personnel practices, the design and construction of facilities, the use of equipment, and other matters affecting sanitation.

FDA's role is to monitor the sanitation conditions of manufacturers through inspections and provide consumers assurances that the industry is meeting its responsibility of producing safe food products. FDA requires each field office to maintain a detailed inventory of food, drug, cosmetic, and medical device establishments subject to inspection under the FD&C Act. The Official Establishment Inventory (OEI) contains information on manufacturing establishments and other firms that are eligible for inspection and provides the principal basis for which planned inspections and inspection resources are allocated to FDA's field offices. The OEI is used in budget presentations to justify current and additional resources. FDA field inspectors are generally not specialized and assigned to one particular product type but may be assigned as needed to provide surveillance over the full range of food, drug, cosmetics, and medical products FDA is responsible for regulating.

When adulterated products or insanitary plant conditions that may cause adulteration are found, products may be voluntarily destroyed or recalled from the market by the shipper or seized by U.S. marshals on orders obtained by FDA from federal district courts. Persons or firms responsible for illegal products may be prosecuted in the federal courts and, if found guilty, may be fined and/or imprisoned. Continued violations may be prohibited by federal court injunctions.

FDA's efforts in the area of food sanitation and quality control are substantial. In fiscal year 1984, FDA budgeted $47.5 million for food sanitation and quality control programs which represents 45 percent of the FDA's Center for Food Safety and Applied Nutrition budget ($106 million) and 12.3 percent of FDA's total budget ($386 million).

OBJECTIVES, SCOPE, AND METHODOLOGY

We concentrated our efforts on (1) determining the nationwide sanitation conditions of food manufacturing establishments, (2) reviewing FDA's efforts for improving the accuracy of the OEI and for ensuring that the food establishments selected for routine inspection were reasonable considering the establishments' percentage of interstate sales, and (3) enforcing GMP regulations. Previous reports issued in 1972 and 1978 included discussions of sanitation conditions in the food manufacturing industry and FDA's surveillance of food manufacturing establishments and efforts to improve the accuracy of the OEI.

To assess the sanitary conditions in the food manufacturing industry, we selected a sample of 500 establishments from FDA's July 15, 1982, OEI which contained 38,077 food manufacturing establishments. On July 16, 1982, FDA field offices were instructed by headquarters to initiate an OEI improvement program that was aimed at removing certain types of manufacturing establishments, primarily small retail establishments, from the inventory. FDA headquarters established a January 1, 1983, completion date for the OEI improvement program. By selecting a July 15, 1982, food manufacturing inventory, we were able to assess the extent to which manufacturing establishments, included in our sample, were removed from the inventory due to the OEI improvement program.

The random sample of 500 establishments was forwarded to all 23 FDA field offices for identifying establishments that were eligible for routine sanitation inspections. FDA field offices reviewed each of the 500 manufacturing establishments and advised us of the establishments that were either (1) out of

business, (2) misclassified as a food manufacturer, (3) manufactured food only for nonhuman consumption, (4) removed from the inventory after July 15, 1982, due to the inventory improvement program, (5) seasonal establishments not in operation, (6) recently inspected and no significant problems were found, or (7) distantly located from FDA field offices. (See enc. I.)

FDA field offices determined that 259 of these 500 establishments did not belong in their food manufacturing OEI primarily because the establishments were out of business, misclassified as food manufacturers, or were firms no longer in the inventory mainly because they were small retail establishments. As a result we estimate, based on our sample, that 19,725 of the 38,077 establishments should not have been included in the food manufacturing OEI. Of the 19,725 establishments, we estimate that 10,357 should have been removed due to the OEI improvement program. (See enc. I.)

In addition, after consulting with FDA officials, we agreed that establishments in our sample should not be inspected by FDA if they either (1) had been recently inspected and no significant problems were found, (2) were distantly located from FDA field offices and such inspection would result in excessive travel costs, or (3) were seasonal and not in operation. Therefore, 89 of the remaining 241 establishments were deleted from our sample primarily for these reasons. Projecting these additional exclusions from the sample, we estimate that for the purposes of this study, the sample universe was reduced by an additional 6,777 establishments. Between February and June 1983, FDA inspected the other 152 establishments included in our sample and its OEI. This report reflects the results of these inspections which are projectable nationwide to 11,575 establishments. (See enc. I.)

We asked FDA to classify the seriousness of insanitary conditions for the 152 inspections using the following criteria:

No Insanitary Conditions.

Minor Insanitary Conditions - Insanitary conditions are minor (not likely to cause product adulteration).

Serious Insanitary Conditions - Insanitary conditions are serious (could reasonably result in or have potential for causing product adulteration).

Very Serious Insanitary Conditions - Insanitary conditions are very serious (have immediate potential or have caused product adulteration).

We reviewed the inspection reports and FDA's classification of each establishment and agreed with FDA's summation of the inspection results.

Similar inspections and classifications were made at our request in 1972 in 21 states by six of FDA's field offices. The results of those inspections could not be projected nationwide. Thus, although the requested inspections were conducted nationwide, statistically valid comparisons of sanitation conditions cannot be made to determine precisely industry's progress in improving conditions between 1972 and 1983.

We obtained information from FDA inspection records on the estimated annual sales volume and the estimated percentage of interstate commerce for the 152 establishments inspected to determine the reasonableness of FDA conducting routine sanitation inspections at these establishments. In addition, we obtained the results of FDA fiscal year 1983 inspections of other food manufacturing establishments from its Program Oriented Data System. FDA uses this information to determine the seriousness of insanitary conditions and the types of corrective actions taken to resolve the problems noted during inspections. We compared this information to the results of our nationwide sample of food manufacturers to determine if there were significant differences in the seriousness of insanitary conditions found.

Also, to determine the enforceability of GMPs we reviewed the legislative history of the FD&C Act, pertinent court cases, and the act's implementing regulations (21 C.F.R. Part 110) and consulted with FDA attorneys concerning this aspect of our review.

Our work was performed in accordance with generally accepted government auditing standards.

SERIOUS INSANITARY CONDITIONS NOT FOUND IN MAJORITY OF FOOD MANUFACTURERS

Based on the results of the 152 nationwide inspections and the classification of the sanitation conditions found, 93 percent[3] of the establishments did not have significant insanitary problems. Specifically, 67 establishments (44 percent) had no insanitary conditions noted during FDA inspections, while 74 establishments (49 percent) were operating with minor insanitary conditions. Serious (8) or very serious (3) insanitary conditions were found at the other 11 establishments (7 percent).

Our nationwide sample, projected to the adjusted universe of 11,575 establishments manufacturing food products, showed that

- --5,103 establishments (44 percent) were operating under sanitary conditions,
- --5,635 establishments (49 percent) were operating under minor insanitary conditions which would not likely result in product adulteration,
- --609 (5 percent) were operating under serious insanitary conditions which could reasonably result in or have potential for causing product adulteration, and
- --228 (2 percent) were operating under very serious insanitary conditions which had immediate potential for or had already caused product adulteration.

Information contained in FDA's Program Oriented Data System showed that 5.1 percent of the food manufacturers inspected in fiscal year 1983 had serious or very serious insanitary conditions.

In 1972, at our request, FDA inspected 97 randomly selected food manufacturing plants in 6 FDA field offices. Based on

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[3]Because we reviewed a statistical sample of food manufacturing establishments, each estimate developed from the sample has a measurable precision or sampling error. The sampling error is the maximum amount by which the estimate obtained from a statistical sample can be expected to differ from the true universe characteristic. In this case it is plus or minus 5 percentage points. Sampling errors are usually stated at certain confidence levels--in this case a 95-percent confidence level.

FDA's classification of the 97 inspections, we reported that 69 percent of the food manufacturing plants had insanitary conditions. These plants were grouped as follows: 29 percent had minor insanitary conditions that were not likely to lead to an adulterated product. The other 40 percent had insanitary conditions which had potential or serious potential for causing product adulteration. FDA, in commenting on the 1972 report, recognized that an increase in its inspection capability was needed to make an impact on improving sanitary conditions.

Insanitary conditions found during FDA's recent inspections occurred in both large and small establishments and covered a variety of products. Six of the 11 establishments operating under serious or very serious insanitary conditions had estimated gross annual sales of less than $0.5 million; two establishments sold between $0.5 million and $1 million worth of food products annually; and three establishments had annual sales of more than $1 million. The products produced by these establishments included bakery products, seafood, coffee, peanuts, and bottled water. The three largest product groups inspected were beverages (32 establishments), bakery products (29 establishments), and dairy related products (24 establishments).

FDA took action to deal with the 11 problem establishments. At each of the establishments, FDA investigators discussed their observations and obtained oral and/or written responses from the establishments' managements on corrective action they had taken or planned to take. Where FDA found adulterated products in 3 of the 11 establishments, 2 of them voluntarily destroyed the products, and a U.S. marshal seized and destroyed the product at the third establishment. Enclosure II provides additional information on the results of FDA's inspections.

ADDITIONAL EFFORTS NEEDED TO VERIFY ACCURACY OF FOOD ESTABLISHMENT INVENTORY

At the time we initiated our review, FDA's OEI was inaccurate and contained establishments that were out of business or misclassified as food manufacturers. As a result of the OEI improvement program, FDA subsequently removed about 34 percent of the food manufacturing establishments from the OEI. These were small retail establishments which FDA believed could more appropriately be inspected by state and local governments. FDA officials advised us that all states have responsibility for conducting food sanitation inspections for food establishments operating within their state boundaries.

In adjusting its OEI, FDA excluded manufacturing-retail establishments, such as bakeries and candy shops, and decided to place more reliance on state and local governments to regulate such establishments. These establishments according to FDA, had annual sales of less than $500,000, and 75 percent of their sales were retail sales within state boundaries. Between July 1982 and January 1984, 12,776, or 34 percent, of the 38,077 food manufacturing establishments were removed from the inventory of food manufacturers. Sixty-one percent of the decrease in food manufacturing establishments occurred within the jurisdiction of 6 of 23 FDA field offices. (See enc. III.)

Other establishments may also have to be removed from the OEI, particularly those that have little or no interstate sales and may be routinely inspected by the state and local governments. For example, our analysis of FDA inspection records for the 152 establishments that FDA inspected for us and that are included in FDA's current OEI showed:

--111 establishments (73 percent) had interstate sales of 50 percent or less,

--85 establishments (56 percent) had interstate sales of 10 percent or less, and

--52 establishments (34 percent) had no interstate sales.

We estimate that of the 11,575 food manufacturing establishments in FDA's inventory that were included in our nationwide sample, 6,473 (56 percent) had interstate sales of 10 percent or less, of which 3,960 (34 percent) had no interstate sales (see enc. IV).

ENFORCEABILITY OF GMPS

Although GMP regulations have been established, there have been questions raised in the private sector concerning whether the regulations are enforceable. FDA issued the GMPs for manufacturing, processing, packing, or holding human food as standards for food establishments to follow as well as for FDA to use in evaluating sanitary practices in the food industry.

FDA views GMPs as having the force and effect of law. Accordingly, FDA believes that deviations from the GMP regulations constitute a violation of section 402(a)(4) of the act; products that are prepared or held under conditions which deviate from the GMP regulations are adulterated under that

section of the statute because such products "may have become contaminated with filth or . . . rendered injurious to health." FDA recognizes that in considering the significance of GMP deviations, and the resulting statutory adulteration, the courts have held that the conditions must be such that they would, with "reasonable possibility," result in contamination.

Based on examination of the legislative history of the FD&C Act and pertinent court cases, we conclude that the courts have recognized that GMPs (21 C.F.R. 110) constitute valid and substantive regulations.[4]

The act prohibits the introduction of adulterated food in interstate commerce. Section 402(a)(4) of the act provides that a food shall be deemed adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may be rendered injurious to health. . . . ." We agree with FDA that in considering the significance of GMP deviations, and the resulting statutory adulteration, the courts have held that the phrase "may have become contaminated"[5] means that, to be violative, the conditions must give rise to more than a "mere possibility" of contamination. Rather, the conditions must be such that they would, with "reasonable possibility," result in contamination.

However, the FD&C Act does not impose any sanctions for departures from GMPs. For example, as noted on page 2, 74 of the 152 establishments FDA inspected for us had deviations from GMPs, none of which would likely result in product adulteration. At each of the establishments where GMP deviations were noted, FDA investigators discussed their observations with the establishments' management concerning corrective actions. FDA attorneys advised us that no legal action has been taken against any establishment based only on section 402(a)(4).

CONCLUSIONS

When we conducted our review in 1972, the sanitation conditions in the food manufacturing industry in 21 states were a significant problem. It appears, based on the 1983 nationwide sample inspections and FDA fiscal year 1983 inspection results,

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[4]See United States v. Nova Scotia Food Products Corp., 568 F. 2d 240, 245-48 (2d Cir. 1977).

[5]See Berger v. United States, 200 F. 2d 818 (8th Cir. 1952).

which showed that 93 percent and 95 percent of the food manufacturers, respectively, did not have significant insanitary problems, that progress has been made to improve the sanitary conditions in food manufacturing establishments.

FDA has also made progress in correcting and adjusting its food manufacturing inventory. Nearly 34 percent of the establishments included in the inventory 2 years ago have been removed from the food manufacturing inventory. For those establishments removed, mainly small retail establishments, FDA will place greater reliance on state and local governments for routine sanitation inspections. The inventory adjustments should enable FDA to develop better and more realistic workplans for allocating inspection resources.

Our nationwide sample of food manufacturing establishments indicates that opportunities exist for FDA to further reduce its inventory. Over half of the establishments included in our sample had less than 10 percent interstate sales and 34 percent had indicated no interstate sales. Routine inspection of these establishments could be left to state and local governments unless FDA finds a compelling need to keep such establishments in its inventory for inspection purposes. With further reductions in its inventory, reductions in workload may be possible. To the extent that this occurs and in view of FDA's responsibilities for inspecting firms in the drug, cosmetic, and medical devices areas, FDA has an opportunity to review its current level of resources for food sanitation and quality control and consider how such resources might best be used.

GMPs provide standards for food establishments to follow in developing and maintaining sanitary practices. They are enforceable under the FD&C Act when there is a reasonable possibility of product contamination as defined by the courts, but the act does not impose any sanctions for FDA's use when GMPs are not followed.

RECOMMENDATIONS TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

We recommend that the Secretary direct the Commissioner of FDA to

--continue to review the current food manufacturing establishment inventory and remove those establishments with little or no interstate shipment of foods unless FDA finds a compelling need for continued inspection of such establishments and

--consider the sufficiency of the current level and allocation of inspection resources devoted to the food sanitation and quality control programs and make appropriate adjustments recognizing the reduced inventory and extent of inspection coverage needed to adequately monitor food manufacturing establishments.

AGENCY COMMENTS AND OUR EVALUATION

HHS, in commenting on the draft, stated that it agreed in principle with our recommendations. HHS stated that FDA has in the past and will continue to review the food manufacturing inventory and add to or remove establishments from it as appropriate. HHS, however, did not concur that a special review of the resources devoted to food sanitation and quality control inspections is necessary at this time. HHS commented that FDA will continue to review resource needs and use based on the current inventory and make any needed adjustments to assure adequate inspection coverage to monitor food manufacturing establishments. In this regard, HHS noted that FDA estimates that less than 5 staff years of inspection time would be consumed for the 6,473 establishments included in our sample that had interstate sales of 10 percent or less. HHS stated that any possible reallocation of staff resources would be made to other higher priorities in FDA's food program.

HHS stated that firms removed from the OEI remain the responsibility of FDA and are subject to inspection based on such factors as the establishments' sales volume, consumer complaints, compliance follow-up to recalls, and state and local inspectional capabilities. HHS stated that FDA has removed thousands of establishments from the OEI because of limited interstate commerce, but it is not prudent to eliminate all establishments on the basis of this single criterion.

We agree that it would not be appropriate to eliminate establishments from the OEI on the basis of that single criterion. However, the OEI may contain as many as 6,473 manufacturing establishments with interstate sales of 10 percent or less which should not be routinely inspected and consequently included in the inventory. Our recommendation recognizes that there may be compelling reasons for FDA to routinely inspect establishments with limited interstate sales. However, these reasons are not noted in the OEI. We believe our recommendation is consistent with the approach FDA initiated in 1982 to remove thousands of small retail bakeries with limited interstate sales from its OEI in order to better allocate staff resources.

At a June 12, 1984, meeting to discuss FDA planned actions to screen its OEI, FDA officials advised us that resource limitations would prevent FDA from establishing a special project requiring field offices to review the entire current OEI to justify the basis for including establishments with limited interstate sales in their OEI. However, as a result of the meeting, FDA agreed to review the 85 establishments included in our sample with interstate sales of 10 percent or less.

On June 19, 1984, FDA field offices were asked to justify the basis for keeping these establishments in the OEI and determine if additional steps should be taken to adjust its food manufacturing inventory. FDA expects to complete its review of these establishments in August 1984. While FDA currently estimates that it devotes about 5 staff years to inspecting establishments with 10 percent or less interstate sales, we believe that only after reviewing the 85 establishments and determining the basis for routinely inspecting them will FDA have sufficient data to accurately determine inspection resource needs.

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We obtained written comments from the Secretary of Health and Human Services on the report's contents (see enc. V). As arranged with your office, unless you publicly announce the contents earlier, we plan no further distribution of this report until 10 days from its issue date. At that time we will send copies of the report to the cognizant Senate and House Committees and Subcommittees; the Secretary of HHS; the Commissioner, FDA; the Director, Office of Management and Budget; and other interested parties.

Sincerely yours,

Richard L. Fogel
Director

Enclosures - 5

ENCLOSURE I

ESTIMATED NUMBER OF FOOD MANUFACTURING ESTABLISHMENTS SUBJECT TO GAO REQUESTED INSPECTIONS

	1 Number of firms	2 Total sample size	3 (1-2) Percent		FDA OEI		Total
Official Establishment Inventory (OEI)							38,077
Establishments which FDA determined should not be inspected							
Out of business	36	500	7.2	X	38,077 =	2,742	
Misclassified as a food manufacturer	69	500	13.8	X	38,077 =	5,255[a]	
Food manufactured only for nonhuman consumption	10	500	2	X	38,077 =	762[a]	
Establishments deleted from active OEI since 7/15/82 due to OEI improvement program	136	500	27.2	X	38,077 =	10,357	
Other reasons	8	500	1.6	X	38,077 =	609[a]	
Subtotal	259	500	51.8	X	38,077 =	(19,725)	19,725
Projected OEI (Universe)							18,352
Establishments which GAO excluded for inspection							
Seasonal establishments not in operation	28	500	5.6	X	38,077 =	2,132[b]	
Recently inspected and no significant problems	42	500	8.4	X	38,077 =	3,198[b]	
Travel too costly	6	500	1.2	X	38,077 =	457	
Other reasons	13	500	2.6	X	38,077 =	990	
Subtotal	89		17.8	X	38,077 =	(6,777)	6,777
Estimated universe subject to GAO requested inspections							11,575

[a]Some of these establishments may have other food related activities and should, accordingly, be reclassified in FDA's OEI.

[b]We estimate that for purposes of this study, adjustments for seasonal operations and recent inspections reduced the OEI from 18,352 to 13,022 establishments.

ENCLOSURE II

RESULTS OF FDA'S INSPECTIONS OF 152 FOOD MANUFACTURING ESTABLISHMENTS

To determine the type and extent of insanitary conditions in the food manufacturing industry, we asked FDA to inspect and classify the seriousness of the conditions found at 152 food manufacturing establishments randomly selected from FDA's OEI. Inspectors in each of FDA's 23 field offices were instructed to conduct comprehensive sanitation inspections using FDA's GMPs as a guide. We accompanied inspectors from three FDA district offices--Detroit, Dallas, and Boston--on nine inspections. FDA headquarters staff from the Investigations and Engineering Branch of the Executive Director for Regional Operations classified the conditions found.

The types and extent of insanitary conditions found varied among the establishments inspected. The determination concerning whether an establishment's insanitary conditions were minor, serious, or very serious was a matter of FDA's judgment under the criteria shown on page 4 of this report. Final classification of insanitary conditions according to FDA depended on the type of establishment, the type and significance of GMP deviations, and their proximity to finished and raw materials. For example, failure to provide handwashing facilities for employees in a bottling plant where bottles are eventually sterilized was not considered as serious a potential health problem as failure to provide handwashing facilities in an establishment where employees handle the product. The types of insanitary conditions found at 85 of the 152 establishments inspected by FDA between February and June 1983 are described below. The remaining 67 establishments were operating under sanitary conditions.

SEVENTY-FOUR ESTABLISHMENTS HAD MINOR INSANITARY CONDITIONS

FDA classified 74, or 49 percent, of the 152 establishments inspected as having "minor" overall insanitary conditions--none of which would likely result in product adulteration. Types of deviations from the GMPs found at the 74 establishments included:

--Absence of towels, soap, hot water, and/or signs instructing employees to wash hands in the restrooms.

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--Dirty or poorly maintained areas (peeling paint) over or around food processing areas.

--Employees not wearing hairnets.

--Accumulation of dust, dirt, food particles, or other debris on food processing equipment or utensils.

--Unshielded light fixtures directly over production area or raw materials.

--Accumulation of unused equipment, boxes, trash, or other debris in or around food processing plant which could provide a harborage for rodents or insects.

EIGHT ESTABLISHMENTS HAD SERIOUS INSANITARY CONDITIONS

According to FDA, 8, or 5 percent, of the 152 establishments had serious insanitary conditions which could reasonably result in or have the potential for causing product adulteration. Products manufactured and estimated annual sales for these eight establishments varied as shown in the following table.

Estimated Annual Sales and Products Manufactured by Establishments with Serious Insanitary Conditions

Establishment #	Estimated annual sales (000 omitted)	Products manufactured
1	$ 25 - $ 50	Egg noodles
2	500 - 1,000	Bakery products
3	100 - 500	Specialty bakery products
4	100 - 500	Crabmeat
5	100 - 500	Peanuts
6	500 - 1,000	Oysters
7	50 - 100	Bottled water
8	5,000 - 10,000	Coffee, peanuts

FDA investigators found the following types of GMP deviations at these eight establishments:

--Evidence of rodent activity in the food storage, processing, and warehouse areas.

--Live insects in food processing areas.

--Avenues for rodent/insect/bird entry into processing areas, from uncovered opened windows, holes in ceiling, roof, wall, and door, and gaps under doors.

--Tall grass and debris outside plant that could become a breeding place or harborage for rodents, insects, or other pests.

--Excessive dust and old product residue on food processing equipment and lack of regular cleaning and sanitizing practices.

--Food products not stored at proper temperatures.

--Improperly stored insecticide.

FDA investigators discussed their observations with the managements of these eight firms and obtained written and/or oral responses concerning corrective actions they had taken or planned to take.

THREE ESTABLISHMENTS HAD VERY SERIOUS INSANITARY CONDITIONS

FDA classified 3, or 2 percent, of the 152 firms as having "very serious" insanitary conditions--conditions which had immediate potential for or had already caused product adulteration. In two cases, the establishments' management voluntarily destroyed or agreed to destroy products, while in the third case a U.S. marshal seized adulterated products. Details of the three inspections follow.

Establishment #1

--The first establishment had estimated sales of between $10 and $25 million. It manufactured institutional foods, including canned apples and tomatoes, salad dressings, condiments, and fruit jellies that were shipped interstate. FDA inspectors had found many of the same sanitation problems on eight previous inspections

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conducted between August 1976 and May 1983. On inspections, in September 1979 and January 1983, FDA inspectors found raw materials adulterated by rodents. In both instances, the raw materials were destroyed.

During the May 1983 inspection, FDA investigators observed the following:

--Dirt was on paper bags of raw materials. These bags were emptied into batches of mayonnaise being produced without being cleaned off.

--Rodent excreta and urine stains were on bags of raw material--100-pound bags of barley and 100-pound bags of corn flour.

--Evidence of rodent activity in the plant included rodent excreta on food storage pallets and rodent foot prints in spilled starch in the storage area.

The establishment's management voluntarily destroyed the barley and corn flour, which could have been contaminated, and promised to correct all other problems.

Establishment #2

--The second establishment had estimated annual sales of between $1 and $5 million and manufactured apple juice, apple cider, and vinegar stock. A prior FDA inspection, about 28 months before the one FDA conducted for us in May 1983, found many insanitary conditions, including six uncovered tanks of vinegar stock; opened, unscreened windows and door, and exposed, hanging pieces of insulation above the apple repacking line.

During the May 1983 inspection, FDA found:

--Fruit fly-type insects (dead and alive) directly on the surface of a 6,000-gallon uncovered tank of vinegar stock and in the vicinity of the tank.

--Various openings which could serve as vermin entryways, including opened, unscreened windows and gaps along doors and walls.

--High weeds and an accumulation of debris on the building exterior.

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A U.S. marshal seized all 6,000 gallons of the adulterated vinegar stock juice, which the firm voluntarily held while FDA processed the seizure action. The establishment's owner said he would repair and close the door gaps and screen the windows.

Establishment #3

--The third establishment was a small retail bakery and sandwich shop which manufactured and sold a variety of bread, rolls, buns, and cakes. It had less than $100,000 estimated annual sales.

Since 1978, this establishment has been inspected five times by the state, under an FDA contract. These inspections revealed a history of poor sanitary practices, including the presence of rodents and beetles. Rodent hairs and insects were found in products collected during a February 18, 1981, inspection. Also, the inspection revealed live beetle-type insects in equipment and utensils drawer and rodent excreta. An August 2, 1982, inspection revealed 30 live beetle-type insects on the floor area.

During the May 1983 inspection, inspectors found live beetle-type insects in four different locations in the process room, and an insect infested bag of donut mix and an insect infested 20-pound pail of flour.

The establishment's owner told the FDA inspector that he voluntarily destroyed the infested donut flour mix and promised to call a pest control company. The FDA inspection report indicated that a letter would be sent to the owner requesting that FDA be notified in writing of the corrective actions.

ENCLOSURE III

DECREASES IN FDA'S INVENTORY OF FOOD MANUFACTURING ESTABLISHMENTS

(between 7/15/82 and 1/3/84)

FDA Field Offices	FDA Food Manufacturing Establishments as of		Establishment decrease		Percent decrease
District (Station)	7/15/82	1/3/84			
Los Angeles	1,268	1,164	104		8
Buffalo	1,325	1,200	125		9
San Francisco	2,149	1,945	204		9
Atlanta	1,767	1,595	172		10
Chicago	1,395	1,184	211		15
Seattle	1,722	1,459	263		15
Newark	1,272	1,047	225		18
Nashville	1,165	898	267		23
Denver	1,428	1,083	345		24
Houston (Station)	848	619	229		27
Baltimore	1,407	1,016	391		28
Orlando	1,603	1,159	444		28
New York	1,018	689	329		32
Cincinnati	1,167	770	397		34
New Orleans	1,734	1,142	592		34
St. Louis (Station)	576	371	205		36
Dallas	1,496	959	537		36
Subtotal				5,040	
Minneapolis	3,048	1,615	1,433		47
Boston	2,611	1 326	1,285		49
Philadelphia	3,156	1,502	1,654		52
San Juan	821	375	446		54
Detroit	3,137	1,403	1,734		55
Kansas City	1,964	780	1,184		60
Subtotal				7,736	
Total	38,077	25,301		12,776	34

PERCENT OF INTERSTATE COMMERCE

FOR MANUFACTURING ESTABLISHMENTS INSPECTED

AND THEIR ESTIMATED ANNUAL SALES VOLUME

Estimated percent of interstate commerce	Estimated number of establishments subject to inspection		Actual number of establishments inspected	Estimated Sales Volume (thousands)										
	Percent	Number		$ 0 to 24.9	$25 to 49.9	$50 to 99.9	$100 to 499.9	$500 to 999.9	$1,000 to 4,999	$5,000 to 9,999	$10,000 to 24,999	$25,000 to 49,999	$50,000 and over	Unknown[a]
0	34.2	3,960	52	4	3	6	12	10	12	3		1	1	
01 to 05	11.2	1,295	17	1	2	1	1	2	9					1
06 to 10	10.5	1,218	16	1			2	2	6	3		1	1	
Subtotal	55.9	6,473	85											
11 to 20	2.6	305	4				1	1	1		1			
21 to 30	4.6	533	7						6	1				
31 to 40	2.0	228	3				1	1						1
41 to 50	7.9	914	12			2	2	2	2		3		1	
Subtotal	73.0	8,453	111											
51 to 60	3.9	457	6					2	3		1			
61 to 70	4.6	533	7					1	1		2	1	1	1
71 to 80	5.9	685	9			1		2	3	1	2			
81 to 90	6.6	762	10					1	3	2	2		2	
91 to 100	5.3	609	8				2		1	2	2			1
Unknown[a]	.7	76	1											1
Total	100.00	11,575	152	6	5	10	21	24	47	12	13	3	6	5

[a]Information not indicated in FDA inspection records.

ENCLOSURE IV

ENCLOSURE V

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

JUN 11 1984

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report "Evaluation of Selected Aspects of the Food and Drug Administration's (FDA's) Food Sanitation Inspection Efforts." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

ENCLOSURE V

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT LETTER REPORT, "EVALUATION OF THE FOOD AND DRUG ADMINISTRATION'S FOOD SANITATION INSPECTION EFFORTS," REPORT NO. HRD-84-65, DATED MAY 11, 1984

General Comments

We have reviewed the General Accounting Office (GAO) draft letter report. We are pleased and agree with GAO's finding that the sanitary conditions of the food industry have improved considerably since GAO's 1972 report on this subject. Insanitary conditions which were found in 40% of food manufacturing establishments in 1972 are now detected in less than 7% of food manufacturers sampled nationwide.

This improvement is largely attributable to the action of the Congress. In 1973, Congress, acting on GAO's recommendation, increased the resources allocated to the Food and Drug Administration (FDA) for food sanitation inspections. That action enabled FDA to improve its food sanitation inspection activities substantially. FDA's utilization of resources during the 1970s contributed to the progress made in improving sanitary conditions and to achieving a high level of nationwide compliance.

As nationwide sanitary conditions in the food manufacturing industry improved, resources committed by FDA to this area decreased through attrition and in some instances reallocation to other higher priority areas. FDA currently devotes about the same amount of resources to food sanitation field inspections as it did before the 1972 GAO report and 1973 increase. However, recent inspection results show that FDA is maintaining the improvements in food sanitation achieved over the past 11 years. FDA will continue to regularly evaluate resource needs in this and all areas of operation and consider any changes that may become necessary.

We agree with GAO's finding on the improvement of the food industry's compliance status and we agree in principle with the other findings and conclusions, but we have some concerns about the statistics and legal interpretations in this report:

1. Obsolete Official Establishment Inventory (OEI) Data

The GAO study is based on outdated and inaccurate data which was used to develop the sample of food establishments. The outdated OEI data showed a total of 38,077 firms subject to FDA inspection. The correct number should have been about 28,000 firms because FDA had reclassified and removed some 10,000 food manufacturing establishments as part of an on-going improvement project prior to the GAO audit. Based on the outdated data, GAO suggested that FDA should develop better and more realistic workplans for allocating inspection resources. FDA had, in fact, already done this prior to the GAO report.

ENCLOSURE V

[GAO COMMENTS:

We believe appropriate adjustments were made to our sample prior to the FDA conducted inspections to reflect the extent to which the inventory was adjusted by the OEI improvement program. In November 1982, we obtained from FDA an OEI showing 38,077 food manufacturing establishments eligible for food sanitation inspections as of July 15, 1982. We were aware at the time of our request that FDA had initiated an improvement program and on August 4, 1982, identified establishments, mainly small bakeries, for possible removal from the OEI pending field office concurrence. FDA field offices were instructed by headquarters to assess for each establishment if continued FDA inspections were warranted. These establishments, however, were not removed from the OEI prior to our audit which began on June 28, 1982.

To obtain a statistically valid nationwide sample of food manufacturing establishments and to assess the extent to which small retail establishments were being removed from the inventory by FDA field offices, we used the July 15, 1982, OEI. Further, we requested all 23 FDA field offices to verify which establishments in our sample were valid candidates for inspection. FDA field offices advised us that 136 of the 500 establishments had been removed from the OEI since July 15, 1982, due to the OEI improvement. Using this data we estimate that 10,357 establishments were deleted from the OEI or about the same number of establishments (10,000 establishments) that HHS advised us that FDA had deleted from its OEI. Therefore, we believe that appropriate adjustments were made to reflect those establishments deleted from the OEI due to the improvement program. Between February and June 1983, FDA inspected 152 establishments at our request. This report reflects the results of those inspections. (See p. 6.)

We did not suggest or recommend that FDA develop better and more realistic workplans for allocating resources. As pointed out on pages 7 and 9, we believe FDA has made progress in correcting its food manufacturing inventory. We further noted that, based on its own data, FDA removed about 34 percent of the establishments that were in its inventory 2 years ago. We believe that such adjustments should result in more realistic workplans which was one of FDA's stated purposes for initiating the OEI improvement program in July 1982.