089465 Chief OMPS

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

MANPOWER AND WELFARE
DIVISION

JUL 3 0 1974

The Honorable Alexander M. Schmidt, M.D.
Commissioner, Food and Drug Administration
Department of Health, Education, and Welfare

Dear Dr. Schmidt:

We have recently completed a survey of the Food and Drug Administration's (FDA) sanitation program for food storage warehouses. During the survey, our representatives accompanied FDA and/or State inspectors on inspections of 22 food storage warehouses in the Seattle and Los Angeles Districts.

While the inspection results indicated that the sanitation conditions of the warehouses in most cases were adequate, FDA inspectors detected rodent and bird infestations in two warehouses in Seattle that resulted in two of the largest food seizures in FDA history. Contaminated food lots were found by FDA at American Wholesale Grocery, a warehouse routinely inspected by FDA, and at Associated Grocers, Inc., a warehouse which the State was responsible for inspecting under FDA contract.

The results of our survey and examination into the circumstances which led up to the seizures indicate that certain factors impacted on the adequacy of inspections of these two warehouses. They are:

--A need for more specific criteria, guidelines, and/or training to assist inspectors in determining the actions to be taken when indications of possible contamination are noted during inspections.

--A need for criteria to establish when follow-up inspections should be performed.

--A need for better monitoring of State inspection programs under FDA contract.

914462 089465

GUIDELINES AND/OR TRAINING NEEDED TO CLARIFY INSPECTION PROCEDURES AND SCHEDULING TECHNIQUES

Chapter 3 of FDA's Inspector Programs Manual lists a number of factors that inspectors should consider in conducting food storage warehouse inspections. These inspections are conducted in two phases. Under Phase I, the inspector is instructed to walk through the warehouse to determine general sanitation, to examine a certain number of products which may be susceptible to contamination, and to note any evidence of rodent, bird, or insect traffic in or around the warehouse. When evidence of such traffic is observed, the inspector is instructed to note whether excreta pellets are new or old.

If no "significant" evidence of insanitary conditions are noted during Phase I the inspector is instructed to terminate the inspection. However, when "significant" insanitary conditions are found, the inspector is instructed to go to Phase II of the inspection which requires full development and documentation of the evidence to show that insanitary conditions have caused, or are likely to cause, contamination of food products.

FDA has not defined, or provided adequate guidance to its inspectors as to the meaning of "significant" insanitary conditions. Such guidance would assist inspectors in determining whether a Phase II inspection is warranted.

In addition, FDA Seattle District Office officials advised us that FDA headquarters had not developed specific guidelines or criteria to assist in determining when follow-up inspections should be performed. According to these officials, supervisory personnel in reviewing inspection reports must rely on their past experience in judging the seriousness of the inspection findings as a basis for scheduling follow-up inspections.

If more definitive guidelines which (1) specified the insanitation conditions that would warrant a Phase II inspection and (2) provided criteria for follow-up inspections within specified times had been available, FDA might have identified the nature and significance of the problem at American Wholesale Grocery at an earlier date.

We selected this 450,000 square foot food storage warehouse at random from FDA's tentative 2-month listing of planned inspections for January and February 1974 and on January 24, 1974, accompanied an FDA inspector on an inspection of this warehouse. During this inspection, FDA found extensive rodent infestation in flour, pet food, and other products. The State of Washington's

Department of Agriculture, at the request of FDA, embargoed about 266,000 pounds of flour and cake mix on January 29, 1974, and FDA later seized about one-half million pounds of pet foods, cake mixes, and various flours worth over $1 million from this warehouse.

The inspection history of American Wholesale Grocery shows evidence of the emergence of rodent problems beginning in early 1973. In January 1973, a Seattle-King County Health Department inspector found "atrocious conditions" including rodent-gnawed foods. Two Phase I inspections by FDA within a month after this incident indicated some rodent activity; however, the FDA inspector concluded that there were no significant problems.

On March 14, 1973, an anonymous telephone caller told FDA that the warehouse was "rat infested and insanitary." FDA made an inspection on March 20, 1973, and noted rodent excreta pellets in at least four different areas of the warehouse and rodent activity on a pallet containing 28 fifty-pound bags of dog food. American Wholesale Grocery officials promised to correct the sanitation deficiencies and voluntarily destroyed the 28 fifty-pound bags of dog food exposed to rodent activity, along with 11 other fifty-pound bags of dog food which were damaged due to improper handling and may have been subjected to rodent contamination.

FDA scheduled a follow-up inspection for October 1973. The inspection was actually made in late November 1973 in conjunction with a product recall. This inspection showed that 45 of about 100 rodent bait boxes located in the warehouse had had recent rodent activity. In addition, a rodent nest was found in the non-food section of the warehouse. FDA again concluded that there were no significant sanitation problems.

Less than 2 months after this inspection, FDA accompanied by one of our representatives inspected the warehouse and reported extensive rodent infestation of various lots of flour, pet food, and cake mixes.

We believe that the November inspection illustrates the need for further guidelines and/or training to assist inspectors in determining when inspections should go to Phase II. Even though the inspector found much evidence of recent rodent activity, he did not go to phase II of the inspection.

In contrast, we noted that California State inspectors, who inspect food storage warehouses in the Los Angeles area under contract with FDA, operate differently when evidence of animal or insect activity is found. We observed on several inspections that when such

evidence was noted, inspectors performed an indepth examination of the affected lots, including in many cases a container-by-container examination.

FDA Seattle Regional Office officials told us that certain circumstances in the Seattle District Office may have influenced the adequacy of the inspection coverage of American Wholesale Grocery. They told us that since mid-1972, many of the experienced inspectors moved from the District to other FDA regional offices or left FDA, and that there has been a complete turnover of supervisory personnel. Also, the District hired 20 new inspectors. Within this time period, FDA headquarters scheduled a large increase in the number of warehouse inspections because of commitments to the Congress. According to FDA records, the Seattle District Office made 620 warehouse inspections in fiscal year 1973, compared to 72 and 19 in fiscal years 1971 and 1972, respectively.

According to the Regional Office officials, a lack of experienced inspectors may have forced the Seattle District Office to assign inspectors who were relatively inexperienced to warehouse inspections. They told us that during 1973 American Wholesale Grocery had been inspected three times by a district inspector having only 6 to 8 months' experience. Regional officials also told us that because of the large number of warehouse inspections that had to be completed and because there were few experienced supervisors and inspectors at the District Office between July 1972 and June 1973, some of the newer inspectors may not have been adequately trained. These officials further explained that because of this workload increase, supervisors may not have been able to adequately review inspectors' warehouse inspection reports in order to determine whether Phase II inspections were necessary. They pointed out that the lack of such training and supervision may have resulted in newer inspectors not knowing when insanitary conditions were significant enough to warrant a more indepth inspection under Phase II.

Conclusions

FDA district office personnel must use considerable judgment and discretion in determining what insanitary conditions would warrant a Phase II inspection and in determining when follow-up inspections should be performed. While judgment is involved in selecting appropriate actions in each case, criteria, guidelines, and/or training should be established to assist the districts in making these decisions.

Although there were warning signals of chronic rodent activity at American Wholesale Grocery as early as March 1973, the inspection procedures in use and/or the training of new inspectors at that time did

not prevent a serious infestation problem from occurring or provide for the initiation of an appropriate regulatory enforcement action until January 1974. In our opinion, corrective action might have been initiated sooner if specific criteria and/or sufficient training had been available to district personnel as to the actions to be taken when signs of rodent activity are observed, including criteria for scheduling of follow-up inspections.

We recognize that the apparent manpower and workload problems may have adversely influenced the region's inspection program. Although it is difficult to determine what effect these circumstances may have had on the quality of inspections, there were questions concerning the adequacy of the training inspectors received before they were sent out on their own, and the degree to which supervisors were able to adequately monitor the inspector's performance and work. We believe, however, that the existence of better inspection criteria, guidelines, and/or training could have minimized the impact of these problems.

Recommendations

Accordingly, we recommend that you:

--Establish more specific criteria and guidelines for inspectors to follow in determining whether a Phase II inspection is warranted in instances where inspection results indicate insanitary conditions having potential for causing, or having already caused, product contamination.

--Evaluate the adequacy of the training program for new inspectors with a view toward redirecting such training efforts that may be considered necessary with regard to Phase II inspections.

--Establish guidelines for district supervisors to use in determining when follow-up inspections should be performed.

NEED FOR BETTER MONITORING OF STATE-INSPECTED WAREHOUSES

During fiscal year 1972, FDA began a program to augment its efforts of inspecting food production and storage facilities by contracting with the States for food sanitation inspections. FDA entered into a contract on June 1, 1973, with the State of Washington Department of Agriculture whereby the State would be responsible for inspecting 154 or about 50 percent of the approximately 300 food storage warehouses in Washington.

The contract provided that FDA could monitor the thoroughness of State inspections throughout the contract period by a variety of quality

control techniques including (1) a review of State inspection reports, (2) joint FDA-State inspections, whereby FDA would observe the thoroughness and adequacy of State inspections, and (3) independent reinspections by FDA of warehouses already inspected by the State. According to the contract, a sufficient number of warehouses may be reinspected by FDA to enable it to evaluate the State's overall inspection performance.

Joint FDA-State inspections for the purpose of evaluating the adequacy of State inspections have not been conducted in Washington and independent reinspections of State inspected warehouses have been limited. Instead, FDA relied heavily on its reviews of State inspection reports to monitor the adequacy of State inspections.

During the period of the contract, FDA's Seattle District Office reinspected only 3 of the 154 warehouses that the State had inspected under the FDA contract. In these three inspections, the District found that the sanitation conditions were about the same as had been reported by State inspectors, except in one case, where State inspectors had failed to inspect a small room containing contaminated food.

These reinspections were made at the direction of FDA headquarters in connection with a limited national reinspection program initiated in March 1974 providing for such inspections of warehouses and other facilities for the purpose of obtaining information needed to evaluate the possible renewal of State inspection contracts in fiscal year 1975. According to FDA headquarters officials, warehouses included under this reinspection program were limited to warehouses that were inspected by the States in February or March 1974 and found to be in compliance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), appropriate State law or both. These officials informed us that the reinspection of warehouses under this program will be completed by August 31, 1974, at which time this phase of the program will be completed.

With regard to the Seattle District Office's reliance on State inspection reports for monitoring the adequacy of State inspections, we believe that the District's experience in early 1974 with a State inspected warehouse (Associate Grocers, Inc.) indicates that State inspection reports may not provide an adequate basis for such evaluations. As discussed below, significant differences were noted between the State and FDA inspection reports for this warehouse.

In January 1974 a State inspector reported that Associated Grocers, Inc., a 600,000 square foot food warehouse located in Seattle, routinely rotated food stocks, stored all food products away from the walls, and kept the outside premises free from spillage, trash, and debris. FDA recognizes these measures as desirable to help prevent contamination of food products.

The District in February 1974 received two anonymous complaints about significant rodent and bird activity and contamination of goods stored at Associated Grocers, Inc. These complaints occurred shortly after extensive newspaper publicity concerning the seizure of contaminated food at American Wholesale Grocery.

Beginning on February 12, 1974, the District spent more than a week inspecting the warehouse and reported among other things, that routine stock rotation procedures had not been established, that foods were stored against the wall, and that trash, debris, and other potential rodent nesting material were present outside the building. The District also found extensive contamination of flour, potatoes, sugar, salt, and other items. On March 1, 1974, FDA seized food in the warehouse worth about $1 million.

Conclusions

The differences between State and FDA inspection reports on Associated Grocers, Inc., and the State's failure to inspect a room at another warehouse, later noted by District inspectors to contain contaminated food, indicates a need for FDA to monitor State inspections more extensively. In the case of Associated Grocers, Inc., the Seattle District Office would not likely have reinspected this warehouse except for the anonymous complaints, because the districts were instructed under the reinspection program to inspect only those warehouses where State inspections in February or March 1974 disclosed no problems.

Recommendations

We recommend that you:

--Develop an effective reinspection program for monitoring the inspection performance of those States under FDA contract.

--Require that FDA inspectors periodically accompany State inspectors for the purpose of evaluating the adequacy of State inspections.

- - - -

We appreciate the cooperation and courtesies extended to us by FDA personnel during our survey and would appreciate being advised of your views and any action you plan to take with regard to the matters discussed in this report.

Sincerely yours,

for Albert B. Jojokian
Assistant Director