

**Memorandum**

AUG 6 1992

Date

From Bryan B. Mitchell *Bryan Mitchell*
Principal Deputy **Inspector General**

Subject Review of Allegations of Mismanagement at the Food and Drug Administration - Newark District Office (A-02-91-02522)

To James O. Mason, M.D., Dr. P.H.
Assistant Secretary for Health

The attached final audit report provides you with the results of our review of alleged mismanagement at the Food and Drug Administration (FDA), Newark District Office (NDO). Congressman John D. Dingell, Chairman, House Subcommittee on Oversight and Investigations (Subcommittee), Committee on Energy and Commerce, requested that the office of Inspector General (OIG) conduct an audit of NDO to: (1) determine if the alleged improper management practices in that office have hindered the enforcement of the Federal Food, Drug, and Cosmetic Act; and (2) render an opinion on whether such practices inhibit the proper inspection of pharmaceutical manufacturers and other firms regulated by FDA.

In a subsequent related request, we were asked to evaluate if a specific investigator was mistreated and if management hindered attempts to complete a field inspection.

We found no evidence to support allegations that NDO management inhibited the proper inspection of generic drug manufacturers and other firms regulated by FDA. However, we found that NDO was operating with 18 percent less investigators than authorized, and 76 percent of the investigators had less than 1.5 years of experience. These factors undoubtedly contributed to the fact that NDO was only able to complete 113 (34 percent) of its 335 budgeted inspections for Fiscal Year (FY) 1991. These are problems that could: (1) adversely impact FDA's ability to complete its mission of regulating generic drug manufacturers and others through inspections; and (2) merit the attention of senior departmental and congressional officials.

We did identify a high turnover rate at NDO, as compared with the turnover rates at three other district offices. However, we found no documentation to support the contention that improper or incompetent management caused qualified investigators to seek other employment.

Page 2 - James O. Mason, M.D., Dr. P.H.

We did not find any records supporting allegations that funds were diverted or financial documents were removed from **NDO** offices to impede FDA's internal financial reviews. However, during our review of expenditure of funds, we found that **NDO** had improperly obligated and expended about \$15,800 of FY 1988 funds.

Regarding one investigator's allegations, we found no documentation that **NDO** management mistreated the employee or hindered attempts to complete an inspection. Contrary to the specific complaints, we determined that the investigator was not: (1) deprived of an inspection diary; (2) required to make unscheduled visits to brief **NDO** management; or (3) replaced by an inexperienced and incapable investigator. In response to the Subcommittee's request that we review this investigator's performance record, we determined that the investigator's record of enforcement actions was the fourth highest among 13 peers between **FYs** 1984 and 1990.

Our report includes recommendations to correct deficiencies noted during our audit. In its June 26, 1992 comments on our draft report, the Public Health Service (PHS) generally concurred with our recommendations. The PHS comments have been incorporated into the Agency Comments and OIG Response section of this report and are included in their entirety in the Appendix.

We would appreciate being advised within 60 days on the status of corrective actions taken or planned on each recommendation. If you wish to discuss our findings further, please call me or have your staff contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at **(301)443-3583**. A copy of this report is being sent to Congressman John D. Dingell.

Attachment

Department of Health and Human Services
**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF ALLEGATIONS OF
MISMANAGEMENT AT THE FOOD AND
DRUG ADMINISTRATION - NEWARK,
DISTRICT OFFICE**



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Principal Deputy Inspector General

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To James O. Mason, M.D., Dr. P.H.
Assistant Secretary for Health

This final report provides you with the results of our review of alleged mismanagement at the Food and Drug Administration (FDA), Newark District Office (NDO). The audit was conducted at the request of Congressman John D. Dingell, Chairman, House Subcommittee on Oversight and Investigations (Subcommittee), Committee on Energy and Commerce.

We were asked specifically to: (1) determine if alleged improper management practices hindered the enforcement of the Federal Food, Drug, and Cosmetic Act (Act) by the NDO; and (2) render an opinion on whether such practices inhibit the proper inspection of pharmaceutical manufacturers and other firms regulated by FDA. Specific allegations of improper management practices were:

The NDO management removed experienced investigators from generic drug inspections and replaced them with newer and less experienced investigators, or harassed investigators to terminate their inspections prematurely.

Management favoritism controlled assignments, leave policies, and promotions.

Funds were diverted and documents were removed from the district office prior to an FDA internal financial review.

High personnel turnover was due to NDO mismanagement rather than the attraction of higher salaries in the private sector.

¹ In the final report, use of the title inspector has been changed to investigator in accordance with the Public Health Service's technical comments.

A specific experienced investigator was mistreated by NDO management. When reviewing this allegation, the Subcommittee requested that we determine: (1) how many times the investigator was recalled to the district office for briefings; (2) who recalled the investigator and for what reasons; (3) how many injunctions and other enforcement actions the investigator was involved in over the past 7 years; and (4) how the investigator compared with peers on the number of enforcement actions.

SUMMARY

Based on the results of our review, we found no support for the allegations of mismanagement or mistreatment of employees. There was no indication in the records that NDO management removed experienced consumer safety investigators from inspections of generic drug firms and replaced them with less experienced staff. Moreover, there was no evidence to support the allegation that NDO management practiced favoritism in the control of assignments, leave policies, and promotions. Further, we did not find any evidence of the removal of financial documents or diversion of funds. However, we did find that NDO had improperly obligated and expended about \$15,800 of Fiscal Year (FY) 1988 funds. An analysis of personnel turnover data showed that personnel losses were mainly due to the attraction of higher salaries offered by the private sector, rather than NDO management practices.

We determined that one investigator's allegations of mistreatment were unfounded in that the investigator in question was not denied the inspection diary, nor was the investigator required to make unscheduled trips to NDO that would have hindered the timely completion of an inspection, as alleged. The Subcommittee requested a comparison of the investigator's enforcement actions and ranking with peers for a 7-year period. Our comparison of the investigator's enforcement actions with inspections during the period (FYs 1984 through 1990) showed that the inspections resulted in an enforcement action 27.3 percent of the time (41 enforcements for 150 inspections). For the 7-year period, the investigator's average ranking was fourth among 13 similarly graded peers in the ratio of enforcement actions to total number of inspections.

The fact that NDO operated with 18 percent less investigators than authorized and most of these investigators were relatively inexperienced, contributed to the fact that NDO was only able to complete 113 (34 percent) of its 335 budgeted inspections for FY 1991. We believe these are potentially

serious problems which could: (1) adversely impact FDA's ability to complete its mission of regulating generic drug manufacturers and others through inspections; and (2) merit the attention of senior departmental officials. We are recommending that you direct FDA to conduct internal control reviews under the Federal Managers' Financial Integrity Act (FMFIA) of their regional and district office responsibilities for performing drug, medical device, cosmetic, and food inspections. We believe these reviews should be scheduled as soon as possible.

The Public Health Service (PHS), in its June 26, 1992 comments on our draft report, generally concurred with our recommendations. The PHS comments have been incorporated into the Agency Comments and Office of Inspector General (OIG) Response section of this report and are included in their entirety in the Appendix. Technical comments provided by PHS have been incorporated where applicable.

BACKGROUND

The NDO is 1 of 21 district offices responsible for enforcing the Act. It is organized into 4 branches (Investigation, Compliance, Product Surveillance and Approval Unit, and Administration) and at the time of our audit, was staffed with 101 employees. As of November 29, 1991, NDO had an authorization of 73 investigator positions to conduct field inspections of establishments under FDA jurisdiction. The Philadelphia District Laboratory supports NDO with specialists who inspect laboratory operations during drug manufacturing firm inspections. Although NDO is located in FDA's Region III, personnel support is provided by Region II Personnel Office in New York City. The NDO is located in West Orange, New Jersey, has sub-offices in North Brunswick and Camden, New Jersey, and carries out FDA inspections in that State. Further, according to NDO personnel, New Jersey is the State with the highest concentration of drug manufacturing firms.

The FDA's regional offices use the Program Oriented Data System (PODS), a management-based computer system, to record information about inspections and investigator performance. Information in PODS identifies all investigators who participated in each inspection. The NDO also maintains Establishment Inspection Reports (EIR) to show inspection results and record job assignments and reassignments. Included in these reports are copies of the "Notice of Inspection" documents, containing the names of all FDA personnel involved in the inspections. These are issued to the firm at the beginning of the inspection, with subsequent notices prepared each time an FDA employee is added to the inspection team. The subsequent notice contains the names of

the newly added members, and each member remaining on the inspection.

Promotions in FDA district offices for investigators are competitive for grades General Schedule (GS)-12 and above. The promotion process requires filing an Application for Federal Employment Standard Form (SF)-171 with the district's personnel office. The SF-171 contains a record of an individual's employment history, education, and awards. The **SF-171's** are then evaluated by an impartial panel and a "Best Qualified" (BQ) list prepared. From this list an individual is then selected for promotion. Between October 1989 and June 1991, NDO management competitively promoted five employees. Noncompetitive career ladder promotions account for the majority of promotions at NDO. For investigators, career ladder promotions are made up to the GS-11 grade level. Career ladder promotions are made when individuals demonstrate that they can perform the duties at the next highest grade and have completed at least 1 year of service at the current grade.

The NDO obligation authority for FYs 1988, 1989, and 1990 were \$267,895, \$293,489, and \$330,566 respectively. Although the obligation authority expires at the close of the FY, regulations provided a 2-year period in which to obtain goods and services ordered during the original FY. Government accounting regulations and FDA's own accounting manual states that funds deobligated after the expiration of the original period of obligational availability revert to the Department of the Treasury (Treasury) and are not available for further obligation.

The FMFIA requires Federal agencies to review their systems of internal control and report on the system's status in accordance with policies and procedures contained in the Office of Management and Budget Circular A-123, Revised. Each agency must develop a 5-year management control plan (MCP) to plan and direct the process for reviewing risk, and identifying and correcting material weaknesses in internal control systems.

OBJECTIVES, SCOPE AND METHODOLOGY

The primary objectives of our review were to determine:
(1) if there was any validity to the allegations of improper management practices or mistreatment of employees; and
(2) whether NDO management practices hinder FDA's ability to enforce the Act.

To ascertain if experienced investigators had been replaced or pressured to terminate an assignment prematurely, we interviewed a sample of current investigators. The

interviewed employees were asked if they had ever experienced such actions. We also reviewed a sample of **EIRS** to determine if the record showed any instances of investigators being removed from inspections.

As a starting point in our analysis of whether **NDO** management practiced favoritism, we analyzed the racial and gender composition of **NDO** to ascertain if there was an obvious pattern of bias present in the district office staff. In our interviews, we also asked employees if they had ever faced discrimination in their assignments and promotions or were denied leave when it was requested. We also reviewed employee leave records, and career ladder and competitive promotions to determine if **NDO** management had shown favoritism in inspection assignments, promotions, and granting annual and sick leave. Selected financial records for **FYs** 1988, 1989 and 1990, with emphasis on procurement transactions, were reviewed to determine if funds had been diverted or improper expenditures had been made. Employees were interviewed to determine if they had knowledge of any improper fund expenditures or unauthorized removal of documents from **NDO** premises.

To determine if personnel turnover at **NDO** was caused by mismanagement, we interviewed former employees to ascertain why they had left **FDA** for employment in the private sector. We also reviewed resignation letters of former employees to determine if reasons cited for leaving supported the results of our interviews. We also compared personnel losses in four other districts with **NDO** losses to determine if high personnel losses were unique to one district or common in other districts.

To ascertain whether a specific **NDO** investigator had been mistreated, we provided the management of **NDO** the opportunity to respond to the alleged types of mistreatment. We verified **NDO's** response to documents used by management to support their response. We analyzed computer-generated data from **FDA's** **PODS** for the purpose of comparing the results of inspections conducted by the subject investigator with the results of inspections by the investigator's peers. For this purpose, we analyzed data for the 7-year period from **FYs** 1984 through 1990.

To assist us in determining vulnerabilities in **NDO's** ability to enforce the Act, we analyzed staffing patterns and experience levels of current employees. We also evaluated **NDO's** ability to meet its annual program goals by analyzing annual work load accomplishments. The **NDO's** work load accomplishments were then compared with the performance of other **FDA** district offices as a measurement of **NDO's** productivity.

Our field review was performed between May and October 1991, at the NDO offices in West Orange, New Jersey. The review was conducted in accordance with generally accepted government auditing standards and included testing of financial operations and management practices related to specific allegations contained in the Subcommittee's request. Our review of internal controls was generally limited to accounting procedures associated with the obligation of funds. The review also included an analysis of NDO personnel and work load statistics.

REMOVAL OF EXPERIENCED INVESTIGATORS FROM DRUG INSPECTIONS AND PREMATURE TERMINATION OF INSPECTIONS

The first allegation contained in the request for audit was that NDO management: (1) removed experienced investigators from drug inspections and replaced them with less experienced staff; and (2) harassed investigators to terminate inspections prematurely. To ascertain the validity of this allegation, we interviewed investigators and analyzed documents that showed which investigators had been assigned to an inspection.

We randomly selected a sample of 10 of 22 NDO investigators who were at grade level GS-9 or higher. The sample was limited to these grade levels because we believed that investigators of lower grades probably would not have worked long enough to have experienced the alleged mismanagement practices. Each of the 10 investigators selected had worked for FDA for at least 2 years (the average was 8.8 years employed as investigators). None of the 10 employees interviewed reported ever being removed from assignments and replaced, or forced to terminate an inspection prematurely. Several employees did report being reassigned temporarily to higher priority assignments, but eventually returned to complete the original inspection.

We also reviewed the inspection history, over a 3-year period, of a random sample of 12 out of 47 generic drug manufacturers located in New Jersey. The FDA computer records showed that 302 inspections had been performed on the 47 generic drug firms during the 3-year review period. A computerized listing extracted from FDA's PODS showed that a total of 72 inspections were performed on the 12 sampled firms during the review period.

A critical item of information captured by PODS is the identification of all investigators who participated in each of the inspections. We used this information as a starting point in substantiating the conclusions reached from the interviews discussed above. For those inspections on which PODS time data showed more than one investigator assigned to the inspection, we reviewed the EIR files which contain all

hard copy documentation relative to the inspection. Included in this file is a copy of the "Notice of Inspection" document, containing the names of all FDA personnel participating in the inspection, which is required to be issued to the firm at the inception of the inspection. A subsequent notice is prepared each time an additional FDA employee is added to the inspection team. The subsequent notices contain not only the names of the newly added members, but must also repeat the names of each previously participating member still remaining on the inspection team. The information contained in these documents, in our opinion, would evidence a removal and replacement of an investigator, in that the replaced investigator's name would not appear on a subsequent notice which would contain the name of the newly assigned investigator. Our detailed review of these documents relative to the selected inspections did not show that any investigators had been replaced during a 3-year period.

FAVORITISM IN ASSIGNMENTS, LEAVE AND PROMOTIONS

It was also alleged that managerial favoritism controlled assignments, leave, and promotions. To analyze the validity of this allegation, we reviewed the racial and gender makeup of NDO staff to determine if there was any evidence of institutional bias which might indicate the existence of such favoritism. We also made a separate analysis of senior grades (GS-11 and above) to determine if any bias was indicated by their composition. Our interviews with 10 selected employees included questions about their experiences with assignments, leave, and promotions. We reviewed career ladder and recent competitive promotions to determine if NDO had followed proper procedures relative to those types of promotions. Employee annual leave records were analyzed to determine if large leave balances were an indicator that employees were not allowed to take leave when they requested it.

The analysis of the racial and gender composition of NDO employees did not disclose any pattern of bias. We found that 55 percent of the total number of employees were female: 62 percent were Caucasian and 38 percent were ethnic minorities². In the senior grades, 53 percent were Caucasian males and 47 percent were female and/or ethnic minorities.

Our interviews with selected employees did not reveal any patterns of favoritism in assignments, annual or sick leave, or promotions. The interviewed employees stated that they:

² Ethnic minorities were defined as noncaucasians. At NDO, ethnic minorities were Asian, Hispanic, or Black.

(1) have received assignments that they like and that would assist them in their career progression; (2) had been allowed to take annual or sick leave when they requested it; and (3) had not been discriminated against in either career ladder or competitive promotions.

Promotions in FDA district offices are competitive for grades GS-12 and above. The first step in the competitive promotion process is to file an SF-171 with the district office's supporting personnel office. The SF-171 is similar to a resume in that it primarily contains a record of an individual's employment history, education, and awards. The applications are then evaluated by an impartial panel and a BQ list is compiled and provided to the selecting official. Based on interviews and his personal knowledge of the qualifications of the employees on the BQ list, the selecting official will choose an employee for the competitive promotion. Between October 1989 and June 1991, five competitive promotions were made in the NDO. Our analysis of the regional personnel office's records for each of the five promotions showed that established rules and procedures had been followed.

Career ladder promotions account for the majority of promotions in a district. For an investigator, career ladder promotions are made up to the GS-11 grade level. The general guideline for career ladder promotions is that the employee must demonstrate that he can perform the duties at the next highest grade and must have 1 year of service at the current grade. We reviewed the career ladder promotions of 47 investigators to determine if employees had been promoted within their career ladder time frames. Our review showed that only three investigators had not been promoted within these time frames. We discussed the case of each of the three investigators with their supervisors. According to their supervisors, the promotions had been delayed because the investigators were not ready to perform the duties at the next higher grade level.

In addition to employee interviews discussed above, we reviewed annual leave records of all employees to determine if management showed favoritism in granting leave. Our review was limited primarily to nonmanagerial employees with large use-or-lose annual leave balances, which could be an indicator that certain employees were consistently denied annual leave. We identified 10 employees with large use-or-lose balances. In our interviews with these 10 employees, all of them stated that they had not experienced any problems with being granted annual leave when they requested it.

DIVERSION OF FUNDS AND REMOVAL OF DOCUMENTS

In the Subcommittee's request, there were allegations that funds may have been diverted and that a large number of documents had been removed from NDO premises prior to an internal review. Our review did not disclose any diversion of funds or that documents had been removed improperly from the district office. However, we did find that approximately \$15,800 had been obligated and expended improperly. Federal Government accounting regulations and FDA's own accounting manual state that funds deobligated after the expiration of the original period of obligational availability revert to the Treasury and are not available for further obligation. We were provided with documents at the start of our audit indicating that funds might have been obligated and expended after obligational authority had expired. Based on this information, we reviewed accounting records maintained by NDO for FYs 1988, 1989, and 1990. The review was limited to the determination of whether funds obligated at the end of each FY were deobligated and subsequently obligated for other purposes. Our analysis showed that for the 3 years reviewed, only FY 1988 funds were obligated and expended improperly.

The NDO was given obligational authority for \$267,895 to support its operations during FY 1988. By the end of FY 1988, NDO's entire budget had been obligated. Of this amount, \$65,000 of obligations for goods and services had not yet been received and/or paid for. Although the obligation authority had expired at the close of the FY, regulations provided for a 2-year period in which to receive or pay for goods and services ordered under the FY obligation authority.

Included in the \$65,000 unliquidated obligation balance were blanket obligations which represented estimates for the costs of certain items such as travel, maintenance, and telephone service which NDO had recorded as an expense, but for which the exact amount was not known when FY 1988 ended. Payments for these items were made against the blanket obligation until all of the past year's expenses were paid. The amount of the estimated obligation should have approximated the actual expenditures, possibly leaving only a small balance. Any funds remaining should then have been deobligated and would have reverted to the Treasury.

We found, that as of January 31, 1990, 16 months after the end of FY 1988, NDO had approximately \$15,800 still unliquidated in its blanket obligations for travel, telephone, and supplies, with no further expenditures anticipated. Accordingly, these funds should have been deobligated and returned to the Treasury. Instead, the remaining funds were reobligated to purchase furniture for \$9,150 and office alterations of \$6,650.

PERSONNEL TURNOVER

The final allegation was that arbitrary and capricious management has driven a large number of experienced employees into private industry. To assess the validity of this allegation, we compared the number of professional employees who had resigned in four FDA districts between the years 1983 and 1990 to determine if large personnel losses were unique to NDO. We also conducted interviews with former employees and reviewed letters of resignation (LOR) to determine why they had left NDO for the private sector.

We determined that NDO had a high personnel turnover rate, when compared with three other FDA district offices (see table below). However, we found no evidence to show that employees were driven from NDO employment because of alleged arbitrary and capricious management practices.

Comparison of Turnover Rates
(FY 1983-1990)

<u>FDA District</u>	<u>Average No. of Employees</u>	<u>No. of Employees Who Left</u>	<u>Turnover Rate (Percent)</u>
New York	170	33	19.4
Philadelphia	103	44	42.7
Chicago	91	19	20.8
Newark	95	56	58.9

To determine why NDO employees left FDA to work in drug manufacturing firms, we interviewed seven former senior level employees. Six of the employees had been named in a list of disgruntled employees compiled by the Subcommittee. These six employees stated that they left for higher pay offered by drug firms. One employee refused to respond to our questions. We also reviewed the personnel files of all 20 employees who had resigned from NDO during FYs 1990 and 1991 to determine from LORs why they wanted to leave FDA. Our review showed that:

- o Eight employee LORs contained only general statements that the employee was resigning.
- o Five employees stated that they were returning to graduate or medical school.

- o Two stated they were going to the private sector for more money.
- o Two left to work in another field, one transferred to the United States Customs Office, one left because of an ill child who needed attention, and one file contained no LOR.

Our interviews and review of **LORs** did not indicate that employees left **NDO** because of arbitrary and capricious management practices by **NDO** officials.

ENFORCEMENT OF THE ACT

The Subcommittee requested that we express an opinion on whether alleged mismanagement practices have hindered the enforcement of the Act by **NDO**. Our review did not reveal any basis for allegations of mismanagement. Accordingly, we could not relate the management practices of the **NDO** with its ability or inability to enforce the Act. However, to evaluate **NDO's** capability to enforce the Act, we reviewed **NDO's** past performance with respect to its ability to meet its budgeted performance goals, and the composition of its current work force used to meet district goals. Our review disclosed a vulnerability at **NDO** which could affect its ability to enforce the Act. We found that **NDO** has a shortage of qualified investigators and a large number of those investigators have limited experience.

The **NDO** is currently authorized 73 investigator positions. As of November 29, 1991, only 60 were on board, or about 18 percent less than were authorized. Coupled with this shortage is the limited experience of investigators who conduct drug firm inspections. Approximately 76 percent of current investigators have less than 1.5 years of experience. The **NDO** and its Regional Headquarters are aware of this problem and have taken steps to minimize its effect. Since October 1, 1991, **NDO** hired 9 new employees as investigators, which brought its personnel strength up to the current number of 60 investigators. The **FDA's** Mid-Atlantic Regional Office transferred 16 investigator positions from its authorization to **NDO** to help with the shortage. To speed up training of new investigators, the **NDO** director has initiated locally sponsored drug and medical device training programs instead of waiting for spaces in **FDA's** national training courses. In addition, **NDO** management has altered its normal policy of providing broad based experience to its investigators and has dedicated some of them to performing only drug inspections.

The impact of the shortage of personnel is reflected in **NDO's** inability to provide inspection coverage to all the drug firms under its jurisdiction. The **NDO** provided us with data showing

that in FY 1991, **NDO's** performance goal was 335 inspections. The data showed that only 113, or 34 percent, of the inspections were completed. This appears to be a problem common to all FDA districts, since, as this data showed, no district was able to meet its goal with respect to the number of inspections planned.

To further evaluate **NDO's** ability to enforce the Act, we reviewed an FDA study entitled, "Measuring Inspectional Productivity, FY 1989 and 1990, Two Methods" which measured the effectiveness and efficiency of all 21 FDA districts. In the study, effectiveness was defined as the number of times an inspection resulted in a serious enforcement action. Efficiency was defined as the number of actual inspections conducted in available time. Our analysis of the report showed that in **FYs** 1989 and 1990, **NDO's** national ranking was eighth and fifth, respectively, in effectiveness of its inspections. However, possibly as a result of its personnel shortage and inexperienced staff, **NDO** ranked 20th and 19th in the number of inspections performed.

An FDA district office's personnel shortage and inability to meet performance goals are two vulnerabilities that should be identified through internal control reviews conducted by the agency as part of its FMFIA process. These are vulnerabilities that could: (1) adversely impact FDA's ability to regulate manufacturers of drugs, medical devices, cosmetics, and foods; and (2) merit the attention of senior departmental officials. However, in a previous OIG review of PHS compliance with FMFIA, we found that PHS' MCP for FYs 1990 and 1991 did not specifically provide for reviews of FDA district office responsibilities for inspection of drugs, medical devices, cosmetics, and foods. Consistent with our findings at NDO, we believe that FDA should, as soon as possible, perform internal control reviews focusing on its regional office responsibilities and performance of inspections.

ALLEGED INVESTIGATOR MISTREATMENT BY NDO MANAGEMENT

In June 1991, OIG received an additional request from the Subcommittee to expand the audit to include a review of the mistreatment of a specific investigator in connection with the inspection of a certain generic drug manufacturer. The alleged mistreatment of this investigator included being: (1) deprived of the use of a diary containing inspection notes needed to complete a draft inspection report; (2) deliberately prevented from completing the inspection in a timely manner because supervisors forced the investigator to make unscheduled trips to the district office for meetings; and (3) replaced on an inspection by another investigator who had to use the diary notes because the replacement investigator

was incapable of completing the inspection independently. Specifically, the Subcommittee requested that we:

(1) determine how many times the investigator was recalled to the NDO from the subject inspection site, who recalled the investigator and for what reason; and (2) determine and compare with the investigator's peers the number of injunctions and other enforcement actions the investigator had been involved in for a 7-year period.

We provided NDO management an opportunity to respond to these allegations and to provide documentation to support their response. We also reviewed the inspection diaries of both the investigator and the chemist who assisted on the inspection. The NDO management admitted that the investigator's diary had been taken away, but that an exact copy, which included all the notes relative to the inspection, had been furnished to the investigator. We compared the original diary to the copy provided to the investigator and found that it contained notes from the start of the inspection, December 12, 1990, to February 14, 1991, 2 days after the investigator was notified of removal from the inspection. If the investigator's diary was the only basis for writing the inspection report, it would appear that the investigator had the necessary information to write a report.

The NDO management told us the investigator was removed because of failure to efficiently perform an inspection at the firm and because, during meetings with district management, the investigator appeared unfocused and unable to summarize what the inspection was going to cover. This, coupled with a complaint from the Philadelphia Laboratory Director on the minimal amount of time being spent in the firm by the investigator, warranted the decision to remove the investigator from this inspection. The NDO management contended that the investigator was not required to make unscheduled trips to the office, but was required to provide NDO management with oral reports about the status of the inspection. The NDO further contended that the reports were made at the district office before the investigator was to report to the inspection location, therefore, the investigator was not recalled from the inspection site. Our review of the investigator's diary supported NDO's contention that the meetings were held prior to going to the inspection site. The diary notes indicated that 4 formal meetings took place to discuss the status of the inspection. Our review of the assigned chemist's diary confirmed that the 4 meetings took place and generally lasted from 1 hour and 15 minutes to 1 hour and 30 minutes.

Our review did not support the allegation that the replacement investigator was not capable of conducting an independent inspection of a drug firm and therefore, needed to use the

original investigator's notes extensively. We ascertained that the replacement investigator had 20 years of experience and was considered a specialist in conducting drug firm inspections. The replacement investigator stated that a review of the former investigator's diary notes was made to determine if there was any **useable** information in the diary before continuing with the inspection. The replacement investigator informed us that there was little **useable** information in the diary and that an extensive inspection would have to be performed. The replacement investigator's contention was supported by the chemist who provided technical assistance for this particular drug inspection. The chemist informed us that 3 additional weeks were required to be spent on the investigation at this firm after the removal of the original investigator.

In regard to the replaced investigator's standing with peers, the following schedule shows the number of inspections performed by the investigator and the enforcement actions³ resulting from this work. As shown in the table below, of 150 inspections performed by the investigator during the 7-year period, 41, or 27.3 percent, of the inspections resulted in enforcement actions. The percentage of enforcement actions to inspections was computed for all 13 similarly graded investigators for this same period. The investigator's overall ranking for the 7-year period, when comparing all percentages, showed that the investigator was ranked fourth. This information is shown in the last column of the table.

Comparison of Enforcement Actions and Peer Group Ranking
Investigator Performance

<u>Fiscal Year</u>	<u>Number of Inspections</u>	<u>Number of Actions</u>	<u>Percentage</u>	<u>Peer Group Ranking</u>
	<u>(A)</u>	<u>(B)</u>	<u>(B/A)</u>	
1984	16	10	62.5	1
1985	23	8	34.8	1
1986	19	3	15.8	7
1987	26	5	19.2	7
1988	21	6	28.6	5
1989	17	3	17.6	10
1990	28	<u>6</u>	21.4	6
	<u>150</u>	<u>41</u>	27.3	4

Based on our review, there did not appear to be any basis for the allegations of mistreatment. The investigator was provided a copy of the diary from which an inspection report

³ Enforcement actions are a(n): (1) "Notice of Adverse Finding" letter; (2) regulatory letter; (3) injunction; (4) product seizure; and (5) legal prosecution.

of' the subject generic drug firm could have been completed; NDO management did not prevent completion of the inspection in a timely manner by forcing the investigator to make unscheduled trips to the district office; and the replacement investigator was a competent, experienced investigator who did not have to rely on the replaced investigator's diary notes to complete the inspection.

CONCLUSIONS

We found no evidence to support allegations that NDO management inhibited the proper inspection of generic drug manufacturers and other firms regulated by FDA. However, we found that NDO was operating with 18 percent less investigators than authorized, and approximately 76 percent of current investigators had less than 1.5 years of experience. Although we did identify a high turnover rate at the NDO office, we found no documentation to support the contention that improper or incompetent management caused qualified investigators to seek other employment.

We did not find any records supporting allegations that funds were diverted or financial documents were removed from NDO offices to impede FDA's internal financial reviews. However, during our review of expenditure of funds, we found that NDO had improperly obligated and expended about \$15,800 of FY 1988 funds.

We found no documentation supporting allegations that management hindered an investigator from performing an inspection. We did not find that the employee was deprived of a diary (NDO did take the diary, but a complete copy was provided to the investigator) or replaced by an investigator incapable of independently completing an inspection. The investigator was asked to brief NDO management on four separate occasions, but these were not unscheduled trips which took the investigator away from the inspection site. This investigator had 41 enforcement actions during the 7-year period, and based on the 27.3 percent of actions resulting from inspections, was ranked fourth among the 13 similarly graded investigators for the entire period.

The fact that NDO operated with 18 percent less investigators than authorized, and most of these investigators were relatively inexperienced, could have contributed to the fact that NDO was only able to complete 113 (34 percent) of its 335 budgeted inspections for FY 1991. We believe that this is a potentially serious problem that could: (1) adversely impact FDA's ability to complete its mission of regulating generic drug manufacturers and others through inspections; and (2) merit the attention of senior departmental officials.

RECOMMENDATIONS

We recommend that PHS direct FDA to:

- Conduct internal control reviews of FDA regional office responsibilities and performance of drug, medical device, cosmetic, and food inspections.
- Remind regions of proper practices for reobligating unused funds that should be deobligated and returned to the Treasury.
- Expedite hiring to fill authorized investigator positions transferred from the Mid-Atlantic Regional Office.
- Continue monitoring corrective actions to increase inspections and meet performance goals.

AGENCY COMMENTS AND OIG RESPONSE

In its June 26, 1992 comments on our draft report, PHS generally concurred with our recommendations. Its complete response is included in its entirety in the Appendix to this report and certain responses are paraphrased in this section.

The PHS concurred with our recommendation to conduct internal control reviews of FDA regional office responsibilities and performance of drug, medical device, cosmetic, and food inspections. According to PHS, in FY 1991, FDA's Office of Regulatory Affairs (ORA) conducted risk assessments of its field investigational program for each of FDA's 21 district offices: and in FY 1992, is conducting internal control reviews of these offices.

The PHS concurred with our recommendation to remind regions of proper practices for reobligating unused funds that should be deobligated and returned to the Treasury. According to PHS, ORA management has reminded all of its regional and district office directors of the requirements to revert funds to the Treasury after the original period of obligational authority. This requirement has also been addressed during training for administrative officers and it is an element of all quality assessments of administrative operations conducted by headquarters personnel. In commenting on this recommendation, PHS stated that ORA had previously discovered the reobligation of unused funds during one of its own quality assurance program assessments. After receiving PHS' comments, we attempted to obtain from FDA a report of such an assessment, but found that there was no written record of ORA's findings and conclusions resulting from its assessment of this issue.

The PHS concurred with our recommendation to fill authorized investigator positions that had been transferred from the

Mid-Atlantic Regional Office, but provided data showing that NDO'S on-board staffing level had actually exceeded its respective authorized FY staffing levels as of the end of FY 1991 and by June 1992. The figures cited by PHS, however, do not include the 16 additional investigator positions assigned by the Mid-Atlantic Regional Office to NDO in order to perform generic drug and new drug inspections. While PHS indicated that the additional positions from the region were not provided until the first quarter of FY 1992, our audit disclosed that these positions were, in fact, provided as early as August 1991.

Regardless of when the additional positions were provided to NDO, the intent of our recommendation was to ensure that NDO has the necessary staffing capability to perform its role in inspecting FDA's regulated industries. Given that the region deemed it important to provide additional resources to NDO, we continue to believe that it is critical for these positions to be filled, particularly when NDO was able to inspect only 34 percent of its budgeted inspections in FY 1991. The PHS response gives the impression of a positive staffing posture at NDO, but it does not provide data showing a commensurate improvement in NDO's ability to meet its work load goals.

The PHS concurred with our recommendation to monitor corrective actions to increase inspections and meet performance goals. It stated that ORA routinely monitors and reports on corrective actions from FMFIA corrective action plans, regional quality assurance program assessments, and on-site reviews.

The PHS provided technical comments to our draft audit report that we have incorporated where applicable. Two of these comments focused on the relevance and accuracy of our discussion of FDA's FMFIA program and MCP. We, therefore, revised our FMFIA discussion on page 12 to reflect our concerns about staffing and work load performance. We continue to believe that these issues should be examined as a part of FDA's ongoing FMFIA responsibilities and incorporated into the MCP.

In another technical comment, PHS stated that NDO had provided us with procurement documents resulting from an ORA quality assurance assessment that had found the same problem of improper reobligation of funds discussed in our report. In actuality, the procurement documents we refer to in the draft report were provided to us by an external source prior to the audit's start. As stated above, FDA did not have documentation of the ORA quality assessment discussing this procurement issue.

Page 18 - James O. Mason, M.D., Dr. P.H.

We would appreciate being advised within 60 days on the status of corrective actions taken or planned on each recommendation. Should you wish to discuss the issues raised by our review, please call me or your staff may contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (301)443-3583.

APPENDIX

JUN 26 1992

Assistant Secretary for Health

Office of Inspector General (OIG) Draft Report "Review of
Allegations of Mismanagement at the FDA Newark District Office"

Inspector General, OS

Attached are the Public Health Service's comments on the
subject OIG draft report. We concur with *the* report's
recommendations and have taken, or plan to take, actions to
implement them.

/s/ James O. Mason

James O. Mason, M.D., Dr.P.H.

Attachment

COMMENTS OF THE PUBLIC HEALTH SERVICE (PHS) ON THE OFFICE OF
INSPECTOR GENERAL (OIG) DRAFT REPORT "REVIEW OF ALLEGATIONS
OF MISMANAGEMENT AT THE FOOD AND DRUG ADMINISTRATION NEWARK
DISTRICT OFFICE." A-02-91-02522

At the request of Congressman Dingell, Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, **OIG** conducted an audit of the Food and Drug Administration's (FDA) Newark District Office to determine if alleged improper management practices in the office had hindered the enforcement of the Federal Food, Drug, and Cosmetic Act. In its review **OIG found no** evidence to support any of the allegations.

The following are our comments on the **OIG's** four recommendations:

OIG Recommendation

We recommend that PHS direct FDA to:

1. Conduct internal control reviews of FDA regional office responsibilities and performance of drug, medical device, cosmetic and food inspections.

PHS Comment

We concur. In Fiscal Year (PY) 1991, FDA's Office of Regulatory Affairs (ORA) conducted risk assessments of its Field Investigational Program for each of the 21 field sites. In FY 1992, ORA is conducting internal control reviews for these same sites. These reviews take place at each district office within the region and include not only the conduct of human drug, medical device, cosmetic and food inspections, but also covers other programs such as biologics, radiological products, and animal drugs and feeds.

OIG Recommendation

2. Remind regions of proper practices for reobligating unused funds that should be deobligated and returned to the Treasury.

PHS Comment

We concur. ORA discovered the reobligation of unused funds described in this report during one of its own quality assurance program assessments. ORA management subsequently reminded all of its regional and district office directors of the requirements to revert funds to the Department of Treasury after the original period of obligational availability. This same requirement has been addressed in training for

administrative officers and is an element of all quality assurance assessments of administrative operations conducted by headquarters personnel.

OIG Recommendation

- 3. Expedite hiring to fill authorized inspector positions transferred from the Mid-Atlantic Regional Office.

PHS Comment

We concur that every effort should be made to expeditiously fill critical vacant positions. The OIG report states that the Newark District Office is understaffed relative to authorized inspector/investigator positions and that most of the encumbered positions are filled by inexperienced staff. To support its position, OIG notes that the Newark office is authorized 73 inspector/investigator positions, but had only 60 positions filled at the end of November 1991.

The OIG's findings regarding authorized positions versus staffing levels reflect a situation that occurred at a specific time and under unique circumstances. This 'snap shot' view does not provide a complete picture of the staffing situation at the Newark office.

The Newark office's authorized positions are described in ORA's Table of Organization. This document is prepared each fiscal year and contains authorized staffing levels, based on ORA's annual work plan, for the various components of ORA. It is approved prior to the beginning of each year by the Associate Commissioner for Regulatory Affairs.

As indicated in the following table, the Newark office has actually exceeded its authorized staffing level for inspector/investigator positions in both Fiscal Year (PY) 1991 and FY 1992 to date:

	End of FY 1991		FY 1992 (as of 6/12/92)	
	<u>Authorized</u>	<u>On-Board</u>	<u>Authorized</u>	<u>On-Board</u>
Newark District Office..,	51	57	54	59

The figures cited in the above table for authorized positions are the ORA-approved staffing targets for the Newark office. The on-board figures represent the actual numbers of inspectors and investigators hired by, and working in the Newark office. Not included in the on-board figures are inspectors or

investigators temporarily assigned to the Newark office from other ORA components such as the Mid-Atlantic Regional Office.

In the first quarter of FY 1992, the director of FDA's Mid-Atlantic Regional Office (which oversees the Newark District Office) decided to augment the Newark office's authorized staffing level for inspectors and investigators by reassigning vacant authorized positions from the Regional Office to the Newark office. The purpose of this reassignment of positions was to assist the Newark office in its performance of generic drug and New Drug Application investigations. Under the Mid-Atlantic Regional Director's reassignment of positions, the target for inspector and investigator positions was raised to 73 for the Newark office. This was the authorized staffing figure that OIG cites in the report.

Before the Newark office could reach this newly authorized staffing level, ORA instituted an ORA-wide hiring freeze. This hiring freeze, which became effective in December 1991, was predicated on the fact that, as a whole, ORA was significantly over its staffing ceiling. ORA remains over its authorized staffing level at the present time.

Currently, both ORA Headquarters and the Mid-Atlantic Regional Office have established a staffing ceiling of 54 positions for inspectors and investigators in the Newark office. As of June 12, 1992, there were 59 inspector/investigator staff on-board. There are no plans to hire additional inspector or investigator staff for the Newark office at this time.

OIG Recommendation

4. Conclude monitoring corrective actions to increase inspections and meet performance goals.

PHS Comment

We concur. To increase inspections and meet performance goals, ORA routinely monitors and reports on corrective actions from Federal Managers' Financial Integrity Act corrective action plans, regional quality assurance program assessments, and on-site reviews.