that these violations relate to the manufacture, distribution, or dispensing of controlled substances, DEA declines to consider them for purposes of determining whether Mallinckrodt's registration would be in the public interest.

The commentor further alleges that there currently exists an adequate and uninterrupted supply of methylphenidate under adequately competitive conditions. Consequently, the commentor claims that registration of an additional manufacturer could lead to an increased threat of diversion. In support of its position, the commentor points to a background paper published by DEA in which DEA voiced concerns about the diversion of methylphenidate. As the commentor itself noted, however, DEA's paper concluded that this diversion results from illegal sales by health care professionals, overprescribing by physicians, and illegal sales by end-users. As the commentor acknowledges, there is little evidence of diversion occurring at the bulk manufacturer level.

The commentor contends that, since currently registered manufacturers of methylphenidate produce an adequate and uninterrupted supply of the drug to meet the legitimate needs of the United States, registration of another manufacturer is not needed. The commentor argues that ''there is no evidence that the registration of Mallinckrodt * * * will have a beneficial effect upon competition.'' The CSA, however, does not demand that such a finding be made before DEA can register a bulk manufacturer. Furthermore, pursuant to 21 CFR 1301.43(b), DEA is not:

> required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

As is discussed above, DEA is confident that registration of Mallinckrodt will not impede DEA's statutory obligation to guard against the diversion of controlled substances.

With respect to 21 U.S.C. 823(a)(3), the commentor questions whether Mallinckrodt will promote technical advances in the art of manufacturing methylphenidate and the development of new substances. Mallinckrodt has been registered with DEA since 1971. In the past 25 years, Mallinckrodt has demonstrated its technical and manufacturing expertise with respect to other controlled substances. Based on this history, DEA is confident that Mallinckrodt will continue this practice if registered to manufacture methylphenidate.

Regarding 21 U.S.C. 823(a)(4), the commentor admits that it is unaware of any prior convictions of Mallinckrodt. DEA has verified that Mallinckrodt and its principals have not been convicted under Federal or state laws relating to the manufacture, distribution or dispensing of controlled substances.

Finally, under 21 U.S.C. 823(a)(6), the commentor again argues that Mallinckrodt's alleged lack of compliance with various FDA regulations indicates that its registration as a bulk manufacturer of methylphenidate would be inconsistent with the public interest. For the reasons set forth above, DEA does not feel that the nature of the noted violations warrants issuing an order to show cause to seek to deny Mallinckrodt's applications.

After reviewing all the evidence, including the comments filed, DEA has determined, pursuant to 21 U.S.C. 823(a), that registration of Mallinckrodt as a bulk manufacturer of methylphenidate is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator hereby orders that the 1996 application submitted by Mallinckrodt for registration as a bulk manufacturer of the listed controlled substances, including methylphenidate, is granted. The Deputy Assistant Administrator declines to take action on Mallinckrodt's 1995 application since, given that Mallinckrodt did not manufacture methylphenidate pursuant to its 1995 application and has since submitted an application for 1996, it is unnecessary to do so.

Dated: July 10, 1996.

Gene R. Haislip,

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 96–18024 Filed 7–15–96; 8:45 am]

**BILLING CODE 4410–09–M**

## Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 26, 1996, and published in the Federal Register on March 4, 1996, (61 FR 8303), MD Pharmaceutical, Inc., 3501 West Garry Avenue, Santa Ana, California 92704, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

| Drug | Schedule |
|---|---|
| Methylphenidate (1724) ..... | II |
| Diphenoxylate (9170) ..... | II |

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of MD Pharmaceutical, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 C.F.R. 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: July 3, 1996.

Gene R. Haislip,

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 96–18023 Filed 7–15–96; 8:45 am]

**BILLING CODE 4410–09–M**

**[Docket No. 94–77]**

## RX Returns, Inc.; Revocation of Registration

On August 15, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to RX Returns, Inc., (Respondent) of Palm, Pennsylvania, notifying it of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, RR0166113, and deny any pending applications for renewal of its registration as a distributor (disposer), under 21 U.S.C. 823(e), as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged in relevant part that:

(1) On March 19, 1992, the Respondent entered into a Memorandum of Understanding (MOU) with DEA, where, in exchange for its receiving a DEA registration as a distributor (disposer) of controlled substances, it agreed to comply with security, inventory, and recordkeeping requirements of a DEA registrant;

(2) In July 1992, a DEA investigation of the Respondent revealed numerous recordkeeping and security violations. As a result, on September 24, 1992, DEA conducted an informal hearing in which the Respondent was given an opportunity to reply to allegations regarding violations of 17 recordkeeping and security requirements.

(3) In lieu of further administrative proceedings, on June 18, 1993, the Respondent entered into a second MOU with DEA, in which it agreed to correct the 17 alleged violations and to comply with laws and regulations relating to the handling of controlled substances.

(4) On May 5, 1994, DEA attempted to conduct an audit of seven controlled substances at the Respondent's firm. However, DEA was unable to conduct the audit based upon the Respondent's failure to maintain records of the receipt, distribution and/or disposal of controlled substances. In addition, DEA again uncovered numerous recordkeeping and security violations, most of which the Respondent had agreed to correct pursuant to the June 18, 1993, MOU.

On September 13, 1994, the Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Philadelphia, Pennsylvania, on June 13, 14, and 15, 1995, and continued in Allentown, Pennsylvania, on July 19 and 20, 1995, before Administrative Law Judge Paul A. Tenney. At the hearing, both parties called witnesses to testify and introduced documentary evidence, and after the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. Both parties were given the opportunity to respond to the other side's brief, and counsel for each side submitted a reply brief. On November 14, 1995, Judge Tenney issued his Findings of Fact, Conclusions of Law and Recommendations, recommending that the Respondent's DEA registration be continued and no action be taken against it. On December 5, 1995, the Government filed Exceptions to Judge Tenney's opinion and recommendation, and on December 15, 1995, the Respondent filed a brief in support of Judge Tenney's opinion and recommendation. On December 20, 1995, Judge Tenney transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 C.F.R. 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, with noted exceptions, the Findings of Fact, Conclusions of Law, and Recommended Ruling of the Administrative Law Judge, and his adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that the Respondent is a disposal company founded in 1989 by Mr. Jeffrey Dershem (President), a registered pharmacist. The Respondent receives pharmaceutical products, to include controlled substances, from various sources or customers, such as health care facilities, retailers, and wholesalers. The substances are accepted for either destruction or for distribution back to the original manufacturer for credit. The President testified before Judge Tenney, stating that the Respondent employed, in either a part-time, full-time, or temporary basis, approximately 60 to 65 people, with a payroll of approximately $1.5 million annually.

In the Summer of 1991, the President contacted the local DEA office concerning an application for a DEA registration to handle controlled substances. He was informed that, because of the unique nature of the Respondent's business, it did not fall under any then existing categories of DEA registrants. After negotiating with DEA personnel, the President was told to apply for registration for the Respondent as a distributor of controlled substances. A local DEA Diversion Investigator consulted with management for the Respondent throughout the pre-registration process. The Respondent's proposed processing and recordkeeping systems initially were found acceptable to the DEA, and a preliminary DEA Certificate of Registration was granted to the Respondent on September 12, 1991.

In March of 1992, the Respondent entered into an MOU with the DEA, which stated that the Respondent would (1) install storage facilities for controlled substances in substantial compliance with the provisions of 21 C.F.R. 1301.71 and 1301.72; (2) maintain complete and accurate records of all controlled substances received, distributed or destroyed as required by 21 C.F.R. Part 1304; (3) inventory all controlled substances received and intended for disposal on a DEA Form 41 or approved equivalent, and comply with the provisions of 21 C.F.R. 1307.21; and (4) advise the appropriate DEA office of security measures to be taken to prevent diversion of the controlled substances awaiting disposal. In return, the DEA agreed (1) to issue a registration for a distributor handling controlled substances in Schedules III through V, to the Respondent, when installed security had been approved by DEA; and (2) to review with the Respondent the adequacy of its proposed recordkeeping system, noting that ''necessary modifications to the system proposed by the [Respondent would] be discussed with [it].'' This MOU was entered into because there were no specific DEA regulations governing disposers of controlled substances in the Code of Federal Regulations. Although not yet finalized, on August 23, 1995, the DEA did publish proposed regulations applicable to disposers of controlled substances. *See* 60 FR 43732 (1995).

On June 22, 1992, the DEA conducted an on-site review of the Respondent's facility. Investigators discovered that the Respondent was storing controlled substances and non-controlled substances together inside the controlled substance cage, in violation of DEA regulations. By letter dated July 22, 1992, the President was reminded that on October 10, 1991, and on June 25, 1992, the DEA had informed him not to store controlled substances and non-controlled substances together, but rather to keep them segregated, as required by 21 C.F.R. 1301.72(b)(8)(ii).

On July 22, 1992, after having provided the Respondent advanced notice, the DEA conducted its first official inspection of the Respondent's facility and business operations. A DEA Diversion Investigator (Investigator) testified before Judge Tenney, stating that the DEA was unable to complete an audit of controlled substances during this inspection because of the Respondent's inaccurate or incomplete records. Further, many recordkeeping and security violations were discovered, including the continued storage of non-controlled and controlled substances together, the lack of an initial inventory of controlled substances, the lack of receiving records and distribution records, the failure to submit ARCOS reports, the failure to record the exact quantity of controlled substances received, and the improper preparation of DEA Form 41. Further, the Investigator testified about the security concerns created by this lack of documentation, stating that such a lack of tracking records created a ''greater likelihood of things being diverted just in between the customer and the firm.'' She concluded that ''[o]verall the [processing] system left a lot of loopholes that an employee could, if they (sic) so felt like it, possibly get access to any of the drugs and the firm would probably not know about it because it sometimes took months for things to be processed even into their computer for them to get an inventory.'' The DEA recorded seventeen violations identified during this inspection.

After being served with a Notice of Hearing listing all seventeen violations, the Respondent met with the DEA at an informal administrative hearing on

September 24, 1992. At this meeting, representatives from the DEA and the Respondent discussed the seventeen violations and the Respondent's proposed remedies for these violations. Specifically, the DEA representatives emphasized that the dates of receipt and shipment of controlled substances, and the maintenance of precise receiving records, were needed accountability systems given the Respondent's business.

As a result of this hearing, the Respondent and the DEA entered into a second MOU, in which the Respondent agreed to correct all seventeen cited violations and to comply with all applicable laws and regulations regarding controlled substances. For example, the MOU notes that the Respondent had (1) ''[f]ailed to properly segregate Schedule 3–5 substances from non-controlled substances, * * * within the DEA approved overnight storage cage as required by 21 CFR 1304.72(b)(8)(ii); (2) ''[f]ailed to maintain receiving records (packing slips, invoices) and DEA–41 destruction forms for at least two years from the date of such record for inspection and copying by employees of DEA, as required by 21 CFR 1304.04(a)''; (3) ''[f]ailed to maintain inventories and records of controlled substances in Schedules 3, 4, and 5 either separately from all other records of the registrant[,] or in such form that the information required is readily retrievable from the ordinary business records of the registrant, as required by 21 CFR 1304.04 ((f)(2)''; (4) (4) ''[f]ailed to maintain on a current basis a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of as required by 21 CFR 1304.21 (a)''; and (5) ''[f]ailed to maintain records showing the actual quantity of controlled substances received, including the date of receipt, as required by 21 CFR 1304.21 (b) and (c).''

This MOU also memorialized the corrective action needed, to include: (1) ''Respondent will obtain receipt documents (i.e., invoices or packing slips) from its suppliers and maintain these records for at least two years from the date of each record for inspection and copying by employees of DEA as required by 21 CFR 1303.04(a)''; (2) ''Respondent will maintain on a current basis a complete and accurate record of each such substance * * * received, sold, delivered, or otherwise disposed of as required by 21 CFR 1304.21(a)''; (3) ''Respondent will maintain records showing the actual quantity (i.e. number of dosage units, volume of liquid, etc.) received, including the date of receipt, as required by 21 CFR 1304.23(b) and (c)''; and (4) ''Respondent will maintain records showing the actual quantities (i.e. number of dosage units, volume of liquid, etc.) of controlled substances distributed to other persons, including the date of distribution, and the name, address and DEA registration number of the person or firm to whom the distribution was made, as required by 21 CFR 1304.23 (b) and (e).'' The agreement also required the Respondent to notify the local DEA office of any proposed change to its current disposal site. This MOU was signed on June 18, 1993.

The DEA allowed the Respondent one-and-a-half years to correct the violations set out in this second MOU, for a second inspection was not conducted until May of 1994. Again, however, the DEA found further problems with the Respondent's processing, recordkeeping, and security systems. The investigators were unable to conduct an audit, initially because of a lack of records showing the date of distribution of the controlled substances from the Respondent's location to other destinations. Also, the DEA noted in relevant part that (1) the Respondent was accepting patient prescription medications for destruction, after having been informed by DEA representatives at the informal hearing that the Respondent was not authorized to accept such medications; (2) the Respondent had not conducted a biennial inventory of all controlled substances in the Respondent's warehouse in September 1993, the date the inventory should have been conducted as required by DEA regulations; (3) the Respondent's computer records had indicated that the Respondent had shipped out controlled substances, although the products actually were found at the Respondent's warehouse; (4) the Respondent had destroyed controlled substances at a destruction site different from the one approved by the DEA, in violation of the second MOU, which had stated that if the Respondent wished to change its disposal site, it was required to first notify the local DEA Division Office; and (5) that the Respondent had constructed a Schedule II vault without prior approval of the local DEA office, for by regulation, any vault that is to be used to store Schedule II controlled substances must first be approved by the DEA before being used for such storage.

Also, the Investigator testified before Judge Tenney, stating that Ms. Smith had informed her that patient prescriptions were not entered in the computer system, although such substance had been received at the Respondent's location. The Investigator stated that this recordkeeping practice led her to the following conclusion:

> If I had been trying to do an audit before this, this would have completely killed it because our audits are basically a record of all controlled substances that go through a company. If things are coming in that we don't know about, then we can't really tell if diversion would be occurring.

Concerning an audit attempt in May of 1994, the Investigator also stated that ''[t]heir records were so bad, I couldn't put together numbers because I had no accurate numbers on a large variety of records * * *. The May, 1994 audit was the follow up to the 1992 audit * * *. Our follow up was to say, enough's enough. We have three years here of a firm not being in compliance.''

However, the Investigator also testified that, since 1992, the Respondent had corrected a prior error by reporting to the ARCOS unit as required. Yet, due to the problems with the actual recording of shipment dates, the Investigator opined that the ARCOS reports were probably inaccurate.

As for other documentary problems, the Investigator also testified that the Respondent's personnel continued to improperly prepare the DEA Form 41, stating that the documents reviewed still failed to accurately reflect burned products and actual quantities of substances destroyed. Specifically, the Investigator recounted that ''I have a whole lot of forms that don't give me the product name, much less an accurate idea of what these numbers represent when they're in the columns saying * * * controlled substance doses [, and] controlled substance use.''

In response, Deborah Smith testified before Judge Tenney, stating that she was the Respondent's executive vice president and general manager, and that she was responsible for insuring that the Respondent's operation complied with DEA regulations and requirements. During the course of her testimony, a videotape, which has been prepared the day before the hearing, was presented. The videotape demonstrated the processes used when a product is returned by a customer to the Respondent's facility. The Investigator confirmed that this product-processing system was in place when she conducted the investigation in January of 1995.

Specifically, as to the handling of controlled substances, Ms. Smith testified that, prior to sending the Respondent pharmaceutical products, a customer had to first contact the Respondent to receive a Return Authorization Number. If controlled substances were to be shipped, the

customer would receive an authorization number ending in a ''5.'' Customers were then sent a return label preprinted with the authorization number, and the customers were instructed to place the label on the front of all boxes. The customer was also sent an information packet, which instructed the customer to conduct an inventory of all scheduled drugs and to send the inventory with any shipment containing controlled substances. Ms. Smith testified that controlled substances received without customer inventories were to be returned to the customer with a letter identifying the flaw in the shipment. The customers were also informed that the Respondent was not authorized to receive Schedule II controlled substances, and if such substances were shipped, they would be returned to the customer. Customers were further instructed to place controlled substances in a sealed pouch in the first box of any shipment. Ms. Smith stated that, when a customer's shipment containing controlled substances arrives at the Respondent's location, the employees in the receiving department note the return authorization number ending in a ''5,'' and know to immediately take the package to the security cage.

Ms. Smith also stated that, after the controlled substances arrive at the security cage, another employee authorized to handle such substances would take a count of all controlled substances. If the physical count did not match the customer's inventory, the Respondent would send the customer a letter identifying the discrepancy. After inprocessing the controlled substances, the product would then be stored in the security cage according to proposed disposition (i.e. return to manufacturer for credit or destroy) until such time as the products would be shipped from the Respondent's facility.

When controlled substance are to be shipped, the product is reinventoried and information regarding the destination of the shipment would be entered into the secured computer system. The controlled substances would then be packaged for shipment inside the cage, taken to the loading dock manager, and put on a truck leaving the facility before the close of that business day. If the products were to be destroyed, they are taken to an incinerator where one of the Respondent's officers, usually the President, would witness the burn. A signed, computer-generated DEA Form 41, would then be sent to DEA, and copies would be retained in the customer's file and at the security cage.

Ms. Smith testified that, if a product was not in its original packaging, the Respondent's personnel would use a reference book to obtain the information needed to complete the computer records as to the identity of the product. Once the information had been located, it would be entered into the computer database so that records for products not in manufacturer packaging contain the same information as records for products in manufacturer packaging. This newly developed system replaced the less precise computer entry of ''repackaged goods,'' which the DEA had found lacked the necessary processing information.

Before Judge Tenney, Ms. Smith addressed the DEA-identified discrepancies. Specifically, she testified that she had understood from discussions with the DEA that the Respondent was allowed to accept patient medications, as long as relevant records were kept separate from the main recordkeeping system. However, after the Investigator informed her that the Respondent was not allowed to accept patient prescriptions under any conditions, the Respondent ceased accepting such drugs. Ms. Smith testified that ''[i]f any of the agents that are at our facility come back and make a recommendation to me, I make a procedural change to accommodate exactly what they want me to do.'' The Respondent also implemented a procedure to return the patient-prescription substances with a reminder to customers, informing them of the Respondent's inability to process such substances.

As to the lack of a biennial inventory in September of 1993, Ms. Smith testified that she had informed the DEA that the Respondent was conducting monthly inventories, and she was under the impression that those inventories would fulfill the biennial inventory requirement. However, Ms. Smith testified, and the Investigator concurred, that after the Investigator informed her of the need for a separate biennial inventory, and after the Respondent's new computer system was in place, such an inventory was conducted in October of 1994.

Ms. Smith testified in great detail concerning the shipping and receiving documents utilized by the Respondent's company personnel. She stated that during the January 1995 inspection, the Investigator's interpretation of the shipping records continued to be misleading. The DEA investigators had failed to ask the appropriate personnel at the Respondent's firm why the shipping records, as read by the Investigator, appeared to contradict the actual existence of the substances under review inside the security cage. For example, in one instance, Ms. Smith testified that the Investigator had misread the computer record, thinking that a substance had been shipped, when in fact it was still at the Respondent's warehouse awaiting the customer's authorization to return the substances. Ms. Smith testified that the shipping records would have shown that the controlled substances in question had never left the warehouse, and, in fact, were awaiting authorization from the customer for the return shipment.

As to the violation of destroying controlled substances at a facility not previously disclosed to the DEA as required, Ms. Smith admitted that the Respondent had sent controlled substances for destruction to a new facility without first notifying the DEA. She stated that the incident had been a trial run because the Respondent needed to find a new destruction site. Due to a change in the municipality code, the prior destruction company was prohibited by law from accepting the Respondent's destruction business.

The Investigator also testified that the Respondent had violated the June 1993 MOU when it had failed to destroy controlled substances during a ten-month period. The MOU stated: ''Respondent will provide periodic monthly reports (DEA Form 41's) of controlled substance disposals to the DEA Philadelphia D.O. Respondent agrees that such disposals will occur on the last Thursday of each month * * *. Respondent does not need to notify the Philadelphia Division Office if it elects not to destroy controlled substances during any particular month.'' Although admitting that ten months had elapsed prior to destruction of controlled substances, Ms. Smith strongly denied that the accumulation of controlled substances for this ten-month period compromised the security of the Respondent's storage cage. She stated that the ten-month period was the time taken by the President to locate, to inspect, and to conduct a background check of another destruction site. Ms. Smith also testified that she had provided DEA with a verbal notification of the change in location, but had not provided written verification. Also, the Investigator had agreed that, after the initial destruction at the previously undisclosed facility, the Respondent had conducted subsequent destructions at a DEA-disclosed facility in compliance with the regulation and the MOU.

As to the problems identified by the Investigator concerning the DEA Form

41, Ms. Smith testified that the old system of handwriting the Form 41's had been changed to a computer-driven process. Specifically, the Respondent's computer system generates the form, and the current process was created and implemented just prior to the May 1994 DEA inspection. Ms. Smith testified that during that inspection, she had showed the Investigator a sample of the new DEA Form 41, and that the Investigator had told her that ''I don't have a problem with it.''

Yet during the hearing before Judge Tenney, the Government presented a DEA Form 41 dated February 28, 1995, stating that the form reflected destruction of ''Repackaged DEA control C-III'' substances. As the Investigator testified, these entries were useless; for, although DEA would know that ''1.00 item'' of a Schedule III substance was destroyed per this document, the DEA still would have no idea what the controlled substance was, what the dosage unit was, and what quantity was contained in the destroyed package. From this document, the DEA remained unable to create an accurate count of the precise controlled substance actually destroyed. Thus, the Investigator concluded that the DEA continued to have problems with the actually completed DEA Form 41's being submitted by the Respondent, despite approving, in theory, their new form.

As to the construction of a Schedule II storage vault, Ms. Smith testified that nothing was stored in that vault. She stated, ''It's not operational in any way, shape, or form.'' Further, the employee who operates the Respondent's controlled substances storage area also confirmed that nothing was stored in the Schedule II storage vault. The Government presented no evidence to the contrary.

As a result of the May 1994 inspection results, the DEA issued an Order to Show Cause, seeking to revoke the Respondent's registration. In response to this order, the Respondent invited the DEA Diversion Investigators to visit its facility for another inspection to verify that the Respondent had achieved compliance with the DEA regulations. The DEA conducted that inspection in January of 1995, and, for the third time, DEA Diversion Investigators inspected the security systems and tried to conduct an inspection of certain controlled substances.

As to the Respondent's receiving and initial customer inventory documents, the investigators found that the Respondent had revised the documents, ''and it looked like the firm was, in good faith, doing everything it could to get such documents from its customers.'' Further, as previously requested by DEA personnel, the Respondent's employees had dated the receiving documents with the actual date of receipt of controlled substances at the Respondent's facility, rather than using the date the substances were being handled and processed at the Respondent's facility. On cross-examination, the Investigator testified that ''the receiving system that the firm had is one thing that I found in January that I felt they had made advances on and that we could accept what they were proposing.''

However, the investigators reported, in significant part, a substantial number of discrepancies still noted during the January 1995 inspection. Specifically, (1) DEA personnel found that the Respondent's records were incomplete and inaccurate, failing to list drug names, correct quantities of products on-hand or shipped, with discrepancies being noted even among the Respondent's own internal tracking documents covering the same period of time. (2) DEA personnel had difficulty tracking controlled substances through the Respondent's records, because the shipping records did not show the date of shipment of controlled substances from the firm. (3) DEA personnel again found Schedule II controlled substances at the Respondent's facility and determined that those substances had been at the Respondent's location for several months. Further, Schedule II products, as well as controlled substances from Schedules III, IV, and V, were found at the Respondent's warehouse in an unsecured area. (4) DEA personnel found that the Respondent had accepted shipments of controlled substances from customers lacking active DEA registrations. Specifically, in one instance a controlled substance was shipped from a company in December of 1994, but that company's DEA registration was retired by DEA on April 1, 1991. (5) Investigators also reported that the Respondent's shipping records failed to show the actual DEA-registered name of some of the receiving registrants. As to this point, the Investigator stated ''I think there's something wrong in the computer system that is giving me a[']shipped to[']name[,] and the firm is saying, 'We don't take back controlled stuff.' ''

Further, the Investigator testified that after the January 1995 inspection, the Respondent's attorney had provided her with an update of the October 1994 biennial inventory. Specifically, she stated that the Respondent's counsel wrote that ''the biennial inventory failed to include 465 items that were on hand prior to October 10, 1994, and 79 items that came into the firm during the two-week inventory period.'' According to the Investigator, such a discrepancy ''[m]akes the inventory [in]complete and inaccurate as far as we're concerned''. The Investigator opined that missing 465 items when taking or recording a physical inventory creates a potential for diversion; for ''somebody could have walked off with all 465 items'' without detection.

However, the Respondent's employee, who had provided the Investigator with a copy of the October 1994 biennial inventory, testified before Judge Tenney, stating that the failure to list the 465 items from a single customer was a result of the Respondent's employees conducting an inventory of those products at the customer's location. Ms. Smith testified that, in this unusual case, this bankrupt customer no longer had employees to conduct the customer-prepared inventory normally required by the Respondent prior to accepting a shipment of controlled substances. Instead, the Respondent's employees had used a stand-alone computer system to enter the date from this inventory, and that data had not been integrated into the Respondent's computer network at the time of the biennial inventory. Rather, the data was maintained on the stand-alone computer system. The employee also testified that the remaining items did not appear on the October 1994 inventory because they were received while the inventory was being taken, and these products had not been counted during the taking of this inventory.

Yet the Investigator testified that the October 1994 inventory was deficient, because it failed to indicate a time certain for accountability purposes, as required by regulation. One of the Respondent's employees testified that in the future the biennial inventory would be conducted over a weekend, when no products would be processed into the Respondent's facility, and the exact time of the inventory would be noted on the report. However, the Investigator also testified that the Respondent had yet to submit a verifiable biennial inventory, as required, despite being registered with the DEA since September 12, 1991. The Investigator testified that, lacking such an inventory, the DEA remains unable to determine whether any diversion of controlled substances has taken place at the Respondent's location.

The Investigator also testified about her efforts to inspect the controlled substances on hand, to determine whether her inspection results would coincide with inspection documents provided by the Respondent. The

documents listed the controlled substances that should be on-hand in the security cage on the day selected for the inspection. However, the Respondent's inventory documents did not match the inventory results reported after DEA personnel conducted their independent physical count of the substances in the storage area.

Ms. Smith testified that on the first day of the January 1995 inspection, she had introduced herself to the DEA inspection team and had informed them that she was the Respondent's contact person during the inspection. However, she testified that the Investigator had failed to inform her of the problems DEA investigators were having in reading the Respondent's reports and collecting the data they needed to complete the controlled substances inspection. Specifically, she stated that the Investigator had reviewed the Respondent's records, noted an inability to determine the name or quantity of specific substances tracked in the records, yet had failed to inform her or any other of the Respondent's management personnel of the problems.

Ms. Smith stated that once she became aware of the specific data the DEA wanted to retrieve from the Respondent's records, she insured that the report contained such information. Specifically, the subsequent report clearly contained the identity of the controlled substance, the quantity, and other pertinent information requested by the DEA personnel. She also testified that such information was recorded in the Respondent's daily records, but that the person preparing the DEA-requested reports had failed to access the various computer fields needed to generate the statistical information sought during the inspection. Further, before Judge Tenney, Ms. Smith reviewed in detail the then current documentation used in the receiving and shipping process, noting that the substances could be tracked if the correct document fields were retrieved to create the report.

An employee of the Respondent's also testified concerning his entry of data, to include the name, strength, and dosage for every controlled substance product received in the secured storage area. He confirmed Ms. Smith's testimony concerning the extent of information recorded in the Respondent's computer system for tracking the processing of controlled substances through the Respondent's facility.

As for the Schedule II substances found by the DEA investigators, Ms. Smith testified that the Respondent's personnel had retrieved six truckloads of pharmaceutical products from a bankrupt customer. The Respondent had contracted to remove all pharmaceutical products from the customer with the exception of Schedule II controlled substances. Security guards at the hospital had informed the Respondent's employees that all Schedule II products had been collected and were stored in a vault at the customer's facility. The Respondent's personnel did not know that there were some Schedule II products intermingled with the truckload of products retrieved until two months after the products had been received and personnel were processing them. Ms. Smith testified that, when the Schedule II products were discovered, the Respondent's personnel promptly shipped them back to the customer's attorney for processing, since the Respondent's registration did not authorize the handling of Schedule II drugs.

The Respondent's personnel did not deny that other Schedule II substances were found at the warehouse in an unsecured area. However, Ms. Smith testified that the boxes containing the Schedule II substances had not been authorized for shipment to the Respondent, and that the boxes were not properly labelled as containing controlled substances. During her testimony, Ms. Smith provided evidence of the Respondent's pre-shipment contact with a customer, but here, since the pre-shipping procedures had with a customer, but here, since the pre-shipping procedures had not been followed by these customers, the Respondent's normal safeguards had failed to prevent the improper storage of the Schedule II substances. At the time of the DEA inspection, the boxes in question had not even been opened, since the Respondent had intended to return all of the unauthorized boxes to the senders. However, since the senders were in bankruptcy status, the Respondent was having difficulties determining were to send the boxes.

Further, as to the shipping of controlled substances to customers lacking active DEA registrations, Ms. Smith denied that the Respondent shipped controlled substances to such entities. She testified that the Investigator had failed to raise this concern to her, and that, if the Investigator had asked her for the shipping information, she could have pulled the shipping document from the computer, which would have reflected that the substances in question had actually been shipped to a location with an appropriate DEA registration number.

As to the receipt of controlled substances from a company lacking a DEA registration, Ms. Smith testified that the intent was always to receive controlled substances only from registered entities. However, in response to the Investigator's concerns, Ms. Smith testified that a procedure was recently adopted that required customers to send a copy of their DEA Certificate of Registration prior to being authorized to actually ship substances to the Respondent's location. The copy, which would reflect the active status of the certificate, is then placed in that customer's file.

Finally, evidence was presented, demonstrating that in October of 1991, the Respondent had hired a consultant (Consultant) to design and develop its computer database system. The Consultant testified before Judge Tenney about the various stages of development and about the on-going modifications required as the company itself developed. For example, in April of 1994, a bar code system was added. Every product processed by the Respondent was labelled with a bar code, and then, ''if the product got misplaced in the warehouse, all the personnel needed to do was pick up the product, scan it in, and the computer would be able to identify where the product belongs, who entered the product, when it was entered [,] and so forth.'' The Consultant testified that this system was implemented as a security measure and to enhance efficiency. The Consultant also stated that, because the Respondent was such a unique business, there was no existing computer software on the market that it could purchase to do its inventory, and that ''it was a very complex system to write.''

The Consultant also testified that, as of October of 1994, the computer system tracks all DEA product coming into the Respondent's facility, shipped out of the facility, or destroyed, and tracks product that remained in the Respondent's warehouse awaiting the customer's disposition orders. He opined that the records related to all of these processes were readily or easily retrievable. He also stated that he had heard the testimony concerning problems in retrieving data at the request of DEA in October of 1994, and he opined that such problems would be common when a company was in the process of making a system conversion such as the one the Respondent was making in October of 1994. In conclusion, the Consultant testified that, given the tests that had been run since the conversion, he was ''confident that DEA products are being tracked accurately from the time they enter the facility until the time they leave.''

The Respondent also presented evidence demonstrating that pre-employment criminal records checks are performed, and that limited access to controlled substances is effectuated by limiting access to the work area where controlled substances are handled and stored. Further, the Investigator testified on cross-examination that the Respondent had installed sufficient physical security equipment.

Pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator may suspend or revoke a DEA Certificate of Registration and deny any pending application for such registration, if he determines that the registrant has committed such acts as would render his continued registration inconsistent with the ''public interest.'' In this case, to determine the public interest, the following factors specified in 21 U.S.C. 823(e) are to be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local laws;

(3) prior conviction record of registrant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety. These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. See Henry J. Schwarz, Jr., M.D., 54 FR 16422 (1989).

Absent evidence which raises the issues of (1) a prior conviction record, (2) compliance, or lack thereof, with State and local law, and (3) the Respondent's past experience in distributing controlled substances, the Deputy Administrator finds that only factors one and five are relevant in determining whether the Respondent's continued registration would be inconsistent with the public interest. As to factor one, ''maintenance of effective controls against diversion,'' the Respondent presented extensive evidence of its current physical security measures, to include a videotape of the exterior and interior of its facility, and testimony concerning its security cage construction. Although there was evidence presented of prior physical security concerns involving the relocation of the security cage, the Investigator testified that such concerns have been remedied by the Respondent's corrective action, to include installation of additional bars over the skylights and mesh over the cage door to preclude theft of controlled substances from the security cage. Further physical security controls were also implemented, to include an extensive bar code system to assist in tracking controlled substances through the Respondent's warehousing process.

However, the Government has presented evidence of a lack of accurate and precise accounting and recordkeeping controls, resulting in the Government's inability to determine whether or not diversion had occurred. Specifically, the Respondent's first biennial inventory was inaccurate and incomplete, for it failed to account for approximately 500 controlled substances. Such a failure puts into question the Respondent's inventory practices, for if those substances were unaccounted for at the time of the inventory, then safeguards to prevent diversion were, arguably, equally ineffective, given the fact that the Respondent failed to identify the actual existence of these substances in its possession at the time of the inventory. Further, although disputed, the Investigatory testified that she was unable to reconcile the Respondent's records with substances on hand when she conducted her inspection in January of 1995. She also testified that, for the four years in which the Respondent had been a registrant, DEA had been unable to ever effectuate an accountability audit. Such a problem again calls into question the Respondent's accountability procedures for keeping an accurate count of controlled substances handled on its premises during any given timeframe. If controlled substances are on the Respondent's premises without knowledge of the Respondent's personnel, then it becomes questionable whether the Respondent's security procedures are adequate to prevent diversion of such unaccounted for controlled substances.

The Government also presented evidence that in January of 1995, Schedule II controlled substances were found on the Respondent's premises, despite the Respondent's lack of authorization to handle such substances. To further aggravate the situation, the substances were found in unopened boxes outside the secured cage, and evidence was presented to establish that they had been in an unsecured location for at least several months. Further, the substances had not been accounted for or processed through the Respondent's records, making their accountability impossible during this time. Such lack of action on the part of the Respondent resulted in a failure of the system to safeguard the substances and to prevent their diversion.

The Respondent's response to the Investigator's testimony was to present evidence that one customer's Schedule II controlled substances were received by Respondent improperly, and that, because of the customer's bankrupt status, the Respondent had had difficulty determining where to return the substances. However, in conflict with this characterization, the Respondent also presented evidence that established that the Respondent's employees had actually conducted an inventory of this customer's returned product at the customer's location prior to boxing and shipping the goods to the Respondent's warehouse. Therefore, the Respondent should have known what substances were in the boxes packed by its own employees. If not, then the unknown boxes perhaps should have been processed first to properly identify what substances the Respondent had taken possession and control of as a result of this business relationship.

The Deputy Administrator finds that the Respondent's failure to know it had Schedule II substances in its possession for several months, coupled with its cavalier storage of unknown substances outside of its security cage, results in a finding that the Respondent has failed to act consistent with the responsibilities inherent in a registrant's status. Specifically, a registrant is charged with knowing, in an expeditious manner, what controlled substances are in its possession, and with affording those substances the necessary protection required to prevent diversion. In this instance, the Respondent did not know it had Schedule II substances, did not open and identify the substances it had received for several months, and had failed to maintain effective controls over these Schedule II substances for a protracted period of time. Such conduct fails to result in ''the maintenance of effective controls against diversion.''

As to factor five, ''such other factors as may be relevant to and consistent with the public health and safety,'' the Deputy Administrator concurs with Judge Tenney's finding that the basis for measuring the success of the Respondent's past experience is rooted in the 1992 MOU, and the 1993 MOU. The Deputy Administrator acknowledges that, at the time of the first MOU, the DEA did not have

regulations in place which specifically addressed the Respondent's business. The MOU acknowledges this fact by stating that ''this registration as a DISTRIBUTOR is an interim measure until such time as the proposed administrative actions are completed. At that time, the distributor registration will be converted to the new category of registration as provided under the law.'' The Deputy Administrator agrees with Judge Tenney's interpretation of this provision of the 1992 MOU, when he writes ''[i]t indicates that the Respondent's business is relatively new, and that the DEA is in the process of proposing guidelines under which to register disposers of controlled substances. Furthermore, * * * [it] suggests that the DEA and Respondent would have to work together [] so that Respondent could fulfill its obligations with respect to the recordkeeping and security obligations of a DEA registrant.''

The record provides evidence of the DEA and the Respondent working together to accomplish the goals of the 1992 MOU. In July of 1992, a DEA inspection resulted in the identification of numerous improprieties, the most significant of which was the DEA's inability to conduct an accountability audit of controlled substances due to the lack of documentation that would facilitate the DEA's need to track the receipt and disposition of controlled substances through the Respondent's facility. The Deputy Administrator agrees that such a lack of verifiable accountability creates a greater likelihood of diversion, for the Respondent, at that time, had not created an accountability system to the degree of specifically needed to maintain a continuous track record of the controlled substances flowing through its facility. Yet, in the spirit of the 1992 MOU, rather than take action to revoke the Respondent's registration, the DEA held in informal administrative hearing on September 24, 1992, resulting in the creation of a second MOU dated June 18, 1993.

The second MOU spelled out 17 problems found by the DEA during the 1992 inspection. Contrary to the testimonial evidence provided by the Respondent's witnesses, the Deputy Administrator finds that these violations are identified with a degree of specificity necessary to enable the Respondent to initiate corrective action. These discrepancies memorialize the fact that the DEA, after conducting an inspection of the Respondent's physical facility and accountability procedures, was unable to conclude that adequate security measures were in place to preclude diversion of controlled substances, because the DEA could not verify through an accountability audit, that the Respondent handled controlled substances in such a manner as to preclude diversion of the substances while in its facility. But the MOU did not stop there, for the parties also memorialized in detail the corrective action the Respondent needed to take.

In May of 1994, the DEA conducted another inspection of the Respondent's facility, and the record demonstrates that the Investigator was again unable to conduct an accountability audit. Although acknowledging the various actions found to be in violation of the 1993 MOU, the Deputy Administrator is most concerned with the inability of the DEA investigators, with the assistance of the Respondent's employees, to conduct an accountability audit. The evidence concerning the imprecise method in which the Respondent documented the controlled substances flowing through its facility during this time, as ''repackaged goods'' lacking an exact identity and count, was justifiably found to be in violation of the agreed accountability procedures defined with specificity in the 1993 MOU.

As to the issue of the construction of the Schedule II vault, the Deputy Administrator agrees with Judge Tenney. Although the relevant rule specifies that a vault must be constructed to certain specifications and approved by the DEA prior to using it to store any Schedule II drugs, the record clearly demonstrates that the Respondent has not stored any Schedule II substances in the vault. Further, Judge Tenney noted that ''21 CFR 1301.71(d) permits, but does not require, registrants to submit proposed security systems to the Special Agent in Charge in the region in which the system is located. * * *'' The Deputy Administrator agrees that ''[s]ince there is nothing in the regulations that requires a registrant to obtain DEA approval before building the vault, there has been no breach.''

The Deputy Administrator also notes that, again in the spirit of cooperation that permeated the relationship between this Respondent and the DEA, the DEA investigators, while this matter was pending before Judge Tenney, again conducted an inspection of the Respondent's facility in January of 1995. Yet against the DEA investigators were unable to complete an accountability audit, finding the Respondent's records incomplete and inaccurate. Specifically, the record contains contemporaneously produced documents for DEA's inspection which lacked quantity counts, stating instead, for example, that a ''repackaged good'' of a Schedule III substance had been destroyed. Such documentation failed to provide the investigator with the exact identity and quantity of the Schedule III substance thus destroyed, in violation of both DEA regulations and the 1993 MOU. Lacking the degree of specificity necessary to enable the DEA investigators to conduct an accountability audit, the records were found deficient. Significant is the fact that the DEA investigators could not reconcile an audit of substances on hand by using the documents presented to the DEA employees for that purpose. From the previous four years of discussions and MOUs, the DEA had clearly defined its concern over the accountability of the respondent for the receipt, processing, distribution, or destruction of controlled substances. DEA's needs were clearly defined, yet the Respondent's personnel were unable to present documents showing that it conducted its business in a manner consistent with the requirements of a DEA registrant.

However, evidence was presented by the Respondent, demonstrating that a multitude of information may have been available at the time of the January 1995 inspection, if the DEA only had requested specific data from the Respondent's employees. A significant issue in dispute in this case was whether the availability of such evidence in the Respondent's computer system equalled the ''readily retrievable'' standard established in DEA regulations for such recordkeeping. The Deputy Administrator agrees with Judge Tenney's conclusion that ''it is implicit from the definition of the term 'readily retrievable' that the DEA recognizes that records may be kept by 'automated data processing systems or other electronic or mechanized recordkeeping systems.' *See* 21 CFR 1304.02(i).'' Further, the regulations specify that ''readily retrievable'' is defined, in relevant part, as requiring certain ''records [be] kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time.'' 21 CFR 1304.029i). However, focusing on the method of storage of data misses the problem here.

The Deputy Administrator disagrees with Judge Tenney's analysis of the application of this standard in this case. Judge Tenney wrote:

> [The Investigator] testified that because the reports did not contain all the necessary information, then that information was not readily retrievable. However, the information for the reports was in the computer and was 'readily retrievable' once it was understood

which 'fields' of information contained in the computer database must be reflected in the reports. Many of Respondent's reports have already been changed to reflect missing information and Respondent appears willing to make any future adjustments to its reports.

Such an analysis places the burden upon the DEA to inform the Respondent as to which ''fields'' of information to include misses the point of the inspection, which is to view the reports used by the Respondent during its normal business activities to track the processing of controlled substances through its facility to insure that the process is effective in preventing diversion of such substances to unauthorized recipients. During an inspection, the Respondent is not asked to create special reports for DEA's use. Rather, the Respondent is to present shipping, receiving, and destruction reports utilized on a daily basis by the Respondent to meet its accountability responsibility as a registrant. Of course such reports may be maintained in an automatic data processing system, but the method of maintenance of the report is not the issue. The issue is the content of the report and its usefulness in demonstrating the Respondent's compliance with DEA requirements in its handling of controlled substances during its daily operation. The DEA merely relies upon the Respondent's existing recordkeeping system to conduct an accountability audit.

However, here the DEA investigators have consistently been unable to use the Respondent's documentation to reconcile the Respondent's accountability records with substances found on hand in the Respondent's security cage on the date of the DEA audit. As of the January 1995 inspection, the Respondent continued to fail to meet this obligation, an accountability obligation levied against any DEA registrant thus handling controlled substances.

Thus, the Deputy Administrator finds that this failure, coupled with the unauthorized storage of unaccounted for Schedule II substances outside a security cage for an extended period of time, create a basis for the revocation of the Respondent's registration. The Respondent had failed to demonstrate that it had maintained effective controls against diversion, and such a failure has created a risk to the public interest.

In mitigation, the Deputy Administrator notes both Ms. Smith's and the President's evidence of continuous attempts to meet DEA's requirements during the course of the meetings and inspections conducted by the DEA. The Deputy Administrator also takes note of the timely and responsive manner in which Respondent's officers modified the firm's business practices to attempt to bring them into regulatory compliance. Their responsive and cooperative attitude indicates a desire and a willingness to operate this returns business in compliance with statutory and regulatory requirements. The Respondent has committed extensive personnel and fiscal resources toward developing a system to insure its operation is in compliance with DEA requirements. Also, the Respondent has initiated procedures, such as employee criminal background checks, to insure that personnel with access to controlled substances within its facility are qualified to meet the responsibilities of such a position.

Further, many of the problems identified in the 1992 MOU and the 1993 MOU have been resolved, such as (1) The Respondent's clearly communicating to its customers its inability to accept Schedule II substances and patient-prescribed substances, and the procedures implemented to return such substances to the customer; (2) fulfilling the ARCOs reporting requirements; (3) separately storing controlled substances and non-controlled substances; (4) correct the Respondent's receiving records to reflect the actual date of receipt of its customer's products; (5) adding the requirement that a customer provide to the Respondent a copy of its DEA Certificate of Registration and an inventory of controlled substances actually shipped to the Respondent; (6) providing DEA notice of its selected disposal site; and (7) modifying the way in which records for repackaged products are created.

Procedurally, Judge Tenney recommended that the Deputy Administrator take no action with respect to the Respondent's registration. After receiving his recommendation, the Government timely filed exceptions, pursuant to 21 CFR 1316.66, and the Respondent field a brief in support of Judge Tenney's recommendation.

After reviewing the parties filings, the Deputy Administrator notes that a significant issue forming the basis of the Government's exception is that Judge Tenney, after reviewing the Respondent's evidence of corrective action taken since the January 1995 inspection, had found such corrective action persuasive in remedying the violations previously identified by the Investigator. Specifically, the Government took exception to Judge Tenney's finding that the Respondent had made reasonable efforts to comply with DEA regulations, given the fact that even as late as the January 1995 inspection, the Investigator had continued to find numerous recordkeeping and security violations. The Government wrote, ''[a]s recent as the July 1995 hearing, the Respondents were still in the process of attempting to bring itself into compliance with DEA requirements * * *. In addition, [the Investigator] testified to matters that remained uncorrected at the firm as of January 1995, and to date, DEA has not been able to conduct an accountability audit at the firm because of the firm's poor record-keeping, (*sic*) nor has the firm produced an accurate and verifiable biennial inventory.'' In a related concern, the Government also took exception to Judge Tenney's finding as to the efforts taken by the Respondent's personnel to create a controlled substance tracking system. The Government wrote that ''there is practically no evidence in the record that [the] Respondent's information system has produced accurate and verifiable information to DEA.''

The Deputy Administrator agrees with Judge Tenney's finding that the Respondent has made efforts to comply with DEA's regulations, as evidenced by the extensive efforts taken to create a computer system that would assist in managing the flow of controlled substances through the Respondent's facility. However, the Deputy Administrator also agrees that the evidence supports the Government's concerns, for DEA has been unable to successfully conduct an accountability audit. The Deputy Administrator agrees that the Respondent's lack of verifiable inventory control places the public at risk from diversion of controlled substances.

The Government also took exception to Judge Tenney's conclusion that the public interest was served by continuing the Respondent's registration, in light of the Respondent's past history of non-compliance with DEA requirements. The Deputy Administrator agrees with the Government's assertion that ''[a]n agency rationally may conclude that past performance is the best predictor of future performance. *Alra* v. *Drug Enforcement Administration,* 54 F.3d 450 (7th Cir. 1995).'' However, here DEA's requirements differ from the average regulatory case, for DEA does not have regulations responsive to and governing the Respondent's business, since this Respondent does not manufacture, distribute, or dispense controlled substances. The terms of the two MOU's and the regulations incorporated into those agreements form the basis for the DEA's regulatory requirements, and both DEA and the Respondent acknowledged the need for

cooperation in applying those requirements as the Respondent's business practices were developed. Although the Deputy Administrator acknowledges that the overall regulatory goal of preventing diversion of controlled substances outside of the regulated system of distribution has applied equally to the Respondent as to any other DEA registrant, from the inception of the Respondent's operation, the mechanisms of compliance have had to be developed. The Deputy Administrator must take these facts into account when reviewing this Respondent's past history of compliance.[1]

Yet the responsibility remains the Registrant's to conduct its business in an accountable manner that does not place the public at risk of diversion of controlled substances. Therefore, in the balance, the Deputy Administrator concludes that it is in the public interest for the Respondent's DEA registration to be revoked. However, the Deputy Administrator feels that the evidence of changes made by the Respondent in response to the Government's case at the hearing before Judge Tenney, may, in operation, finally create an accountability system adequate for the Respondent to demonstrate the requisite degree of precision in handling controlled substances necessary to continue in operation as a disposer. The Deputy Administrator also finds that it is in the public interest for the Respondent to be given yet another opportunity to demonstrate that the latest alterations to the Respondent's business practices will adequately contain the risk to the public of diversion from the Respondent's operation.

Therefore, the Deputy Administrator will stay the revocation and impose a one-year probationary period to determine whether the Respondent can now fully comply with all DEA recordkeeping, reporting, and security requirements. During the one-year probationary period, DEA will conduct inspections and audits in compliance with the procedures established in 21 U.S.C. 880 and its implementing regulations. It is significant that during this period, the Respondent will be taking its second biennial inventory, which will afford the Respondent the opportunity to demonstrate its ability to conduct a meaningful inventory of controlled substances in its possession.

[1] The remaining Government exceptions, and the Respondent's reply to those exceptions, have been previously addressed in this opinion, and they require no further discussion here.

However, if the DEA's inspections or audits reveal either new or repeated violations, the Deputy Administrator will remove the stay and the DEA Certificate of Registration will be revoked immediately, and all pending applications for renewal will be summarily denied. If, however, at the end of the one-year period, the Respondent successfully demonstrates its compliance with the DEA's regulatory requirements, then the Deputy Administrator will withdraw this order and will permit the Respondent to retain its registration, and to renew it, if necessary, at that time.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 CFR 0.100(b) and 0.104, hereby orders DEA Certificate of Registration RR0166113, issued to RX Returns, Inc., be, and it hereby is, revoked and any pending applications for renewal are denied. It is further ordered that this revocation order will be stayed for a period of one year from its effective date. If during the one-year probationary period, the Respondent is found to have violated any DEA reporting, recordkeeping, or security requirements, the previously imposed stay will be removed, the Respondent's DEA Certificate of Registration will be revoked, and any pending applications for renewal will be summarily denied. This final order is effective August 15, 1996.

Dated: July 5, 1996.

Stephen H. Greene,

*Deputy Administrator.*

[FR Doc. 96–18025 Filed 7–15–96; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF LABOR

### Office of Workers' Compensation Programs; Report of Computer Matching Program Between Department of Labor and Social Security Administration

*Participating Agencies:* The participating agencies in this computer matching program are the Office of Workers' Compensation Programs, Department of Labor (DOL) and the Social Security Administration (SSA). This Notice is published as required by the Computer Matching and Privacy Protection Act of 1988, as amended. A new written agreement for this longstanding computer matching program recently has been approved by both the Department of Labor and the Social Security Administration Data Integrity Boards.

*Purpose of Match:* DOL will conduct a computer matching program of DOL and SSA records of Black Lung benefit recipients in order to detect individuals who might improperly receive dual Black Lung benefits from SSA and DOL. When a verified match occurs, the case will be referred to the proper DOL office for development to assure the validity of the match and to make any required benefit adjustments. The SSA data will contain the date of death of SSA beneficiaries. This information will help to minimize those cases in which benefit payments are made to deceased beneficiaries, by identifying a DOL beneficiary who has died, but DOL has not been notified of the death. The SSA data also will assist DOL in properly referring inquiries and correspondence received at DOL regarding SSA-only Black Lung beneficiaries.

*Authority for Conducting the Matching Program:* Title IV of the Federal Mine Safety and Health Act, 30 U.S.C. 901, et seq.

*Categories of Records and Individuals Covered:* SSA, as the source agency, will provide DOL with its Black Lung Payment System, HHS/SSA/OSR 09–60–0045, (52 FR 9543, March 25, 1987), which will be matched with DOL's Office of Workers' Compensation Programs' Black Lung Benefit Payment records contained in DOL/ESA–30 (55 FR 7131, February 28, 1990). The individuals covered will be DOL and SSA Black Lung beneficiaries.

*Inclusive Dates of the Matching Program:* The Matching program will begin either 30 days after the publication date of this Notice, or 40 days (whichever is later) after a copy of the written agreement for this matching program is sent to the Chairman of the Committee on Government Affairs of the U.S. Senate, to the Chairman of the Committee on Governmental Reform and Oversight Operations of the U.S. House of Representatives and to the Office of Information and Regulatory Affairs of the Office of Management and Budget. The matching program will continue for 18 months from the beginning date and may be extended for an additional 12 months thereafter.

*Address for Receipt of Public Comment:* Shelby Hallmark, Acting Director, Office of Workers' Compensation Programs, 200 Constitution Avenue, N.W., Washington, D.C. 20210, Telephone: (202) 219–7503.