Drug	Schedule
Phenmetrazine (1631)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Alphaprodine (9010)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Benzoylecogonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Morphine (9300)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The firm plans to manufacture small quantities of the listed controlled substances to make deuterated and non-deuterated drug reference standards which will be distributed to analytical and forensic laboratories for drug testing programs.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Radian International LLC to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Radian International LLC on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 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: September 17, 1999.

John H. King,

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

[FR Doc. 99–25359 Filed 9–28–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 94–77]

RX Returns, Inc.—Continuation of Stay of Revocation

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), pursuant to 21 U.S.C. 823(e), for reason that Respondent's continued registration would be inconsistent with the public interest.

Respondent timely filed a request for a hearing, and following prehearing procedures, a hearing was held on June 13, 14, 15, and August 19 and 20, 1995, before Administrative Law Judge Paul A. Tenney. On November 14, 1995, Judge Tenney issued his Findings of Fact, Conclusions of Law and Recommendations, recommending that Respondent's registration be continued and no action be taken against it.

On July 5, 1996, the then-Deputy Administrator issued a final order finding that it was in the public interest to revoke Respondent's registration, but to stay the revocation for one year, giving Respondent the opportunity to demonstrate that its recent changes to procedures, ''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.'' RX Returns, Inc., 61 FR 37081 (July 16, 1996). The then-Deputy Administrator further stated that during this one-year period DEA would conduct inspections and audits of Respondent and specifically stated that:

> * * * [I]f 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.

Id. at 37,090.

On May 1, 1997, the Government filed a Motion to the Deputy Administrator for Removal of Order to Stay Revocation, alleging that a DEA inspection of Respondent's facility conducted between September 10, and October 3, 1996, revealed various regulatory violations. By letter dated June 20, 1997, Respondent filed its response to the Government's motion.

By letter dated July 3, 1997, the then-Acting Deputy Administrator advised Administrative Law Judge Mary Ellen Bittner that it appeared that there was a factual dispute as to whether there had been any violation of DEA regulations. Accordingly, the then-Acting Deputy Administrator remanded the matter to the Administrative Law Judge ''to conduct a hearing and make recommendations as to whether a violation has occurred since the effective date of the final order, and if so, whether such violation warrants the removal of the stay.''

Following prehearing procedures, a hearing was held before Administrative Law Judge Mary Ellen Bittner on September 3 through 5, 1997, in Arlington, Virginia. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument.

On May 26, 1999, Judge Bittner issued her Supplemental Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision recommending that the Deputy Administrator withdraw the earlier final order, permit Respondent to retain its registration, and grant any pending applications for renewal of its registration. On June 15, 1999, the Government filed exceptions to Judge Bittner's opinion and recommendation, and on July 8, 1999, Respondent filed its response to the Government's exceptions. On July 9, 1999, Judge Bittner transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 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 adopted 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 findings of fact and conclusions of law which led to the revocation of Respondent's DEA Certificate of Registration and the stay of the revocation are set forth in great detail in the final order of the then-Deputy Administrator found at 61 FR 37081 (July 16, 1996). They will not be repeated in this final order, but are incorporated herein and will be referred to as necessary in rendering a decision in this matter. The issue now is whether any violations of the law and regulations have occurred since the previous final order and, if so, whether such violations warrant the removal of the stay and revocation of Respondent's registration.

As background, the Deputy Administrator finds that Respondents is a disposer of products, including controlled substances, for customers such as health care facilities, retailers and wholesalers. Respondent either destroys the products or distributes them back to the original manufacturer for credit. Jeffrey Dershem owns approximately 55 percent of the shares of the firm and is the president and chief executive officer of Respondent. His wife, Deborah Dershem, (who was known in the previous proceeding as Deborah Smith), owns the other 45 percent of the shares and is Respondent's executive vice president and general manager. Ms. Dershem is responsible for Respondent's daily operations.

Pursuant to the Controlled Substances Act DEA register manufacturers, distributors, and dispensers of controlled substances. Respondent's business does not fit within any of these registrant categories, yet DEA nonetheless issued Respondent a registration as distributor in 1991. Subsequently, in March 1992, DEA and Respondent entered into a Memorandum of Understanding which indicated that due to environmental concerns it has become difficult to dispose of controlled substances. As a result, ''* * * DEA has initiated steps to amend the [Controlled Substances Act] or regulations, permitting a new category of registrant. This new type of registrant would have controlled substance disposal as its primary function. Because of the need for this type of activity, this Memorandum of Understanding (MOU) will serve as an interims step in addressing this particular disposal problem.'' Pursuant to the Memorandum of Understanding, Respondent basically agreed to comply with security, recordkeeping and destruction regulations, and DEA agreed to issue Respondent a registration once its physical security was approved and to work with Respondent to establish appropriate recordkeeping procedures.

On August 23, 1995, DEA published proposed regulations applicable to disposers of controlled substances. See 60 FR 43732 (1995). However, as of the date of the hearing in this matter, these regulations have not been finalized. Therefore, there are still no regulations in effect relating specifically to disposers of controlled substances.

The Deputy Administrator finds that Respondent's business is quite different from other registered distributors of controlled substances. Regular ''forward'' distributors order and receive full containers of controlled substance from their suppliers and, in turn, distribute full containers to customers who order them. According to Mr. Dershem, Respondent, on the other hand, receives ''packages that are open, broken, no longer in shelf packs, bags of pill, boxes of pills, pills that have been repackaged, pills that have been taken out of the original containers and put into hospital containers, things of that sort.''

Ms. Dershem testified at the hearing before Judge Bittner that Respondent prepared a form for its customers to use to list all controlled substances in each box shipped to Respondent, and that a copy of the form was to be placed in the box. This form will hereinafter be referred to as receipt document. According to Ms. Dershem, as of September 1996, Respondent's standard operating procedure when a package containing controlled substances arrived at the facility was that the Respondent's employees opened the box, checked for the document listing the contents of the box, and removed any non-controlled substances or Schedule II controlled substances from the box. Respondent's personnel then counted every dosage unit of each controlled substance received in a box, corrected the inventory listed on the receipt document if necessary, and signed the receipt document as verified. The information is then entered into Respondent's computer and the receipt document filed. If no receipt document is received from a customer, Respondent's computer-generated report becomes the primary document of receipt. Then depending on whether the controlled substances are to be shipped to the manufacturer or be destroyed. Respondent would generate a shipping document or a DEA destruction form.

Following the issuance of earlier final order in this matter, Respondent requested a meeting with DEA representatives. The meeting occurred on August 2, 1996, during which it was discussed, among other things, how Respondent should handle unsolicited shipments, shipments that are not accompanied by the appropriate documents, and shipments that were larger than anticipated. In a letter memorializing her understanding of the results of the meeting, Mr. Dershem stated that ''DEA recognizes that [Respondent] is unique with regard to DEA licensing classification * * *. DEA will work with [Respondent] in understanding our specific business and necessary accommodations.''

Ms. Dershem testified that Respondent was concerned that the receipt document sent by a customer who shipped a controlled substance to Respondent would be considered Respondent's record of receipt, because Respondent would be held accountable for any errors or omissions the customer made in preparing the form. Respondent wanted DEA to consider the document Respondent generated after it inventoried the product as its record of receipt. However, DEA representatives took the position that the proper receiving document is either an invoice or a packing slip that accompanies the controlled substances. But, it is undisputed that the DEA representatives assured Respondent that it would not be held accountable for errors made by customers, and that it would be acceptable for Respondent to attach its computer generated record to the receipt document from the customer.

Regarding large shipments, Respondent emphasized at the meeting that it had a limited number of employees who had undergone background checks and therefore were certified to work in the controlled substance cage, and that it takes a long time to accurately process such a shipment. According to Ms. Dershem, the DEA supervisor present at the meeting indicated that she understood the problem and ''we were given a variance,'' but that Respondent was not told what DEA considered the most important steps in handling large shipments. According to DEA representatives who were present at the meeting and who testified at the hearing, they explained to Respondent that DEA understood that sometimes Respondent could not immediately reconcile what was actually in the

shipment with the documents accompanying it, but that Respondent should at lest open the boxes immediately and determine whether they contained the receipt document from the customer.

On September 10, 1996, DEA began an inspection and accountability audit of Respondent. Prior to the inspection, DEA investigators had decided to audit six different controlled substance products. When the DEA investigators arrived at Respondent they found approximately 1,400 to 1,500 boxes in the controlled substance cage. It was determined that the vast majority of these boxes were part of a shipment that contained products from Kmart, and that only approximately 40 boxes were not part of the Kmart shipment.

It appears that all Kmart pharmacies were going to conduct a physical inventory on July 31, 1996. In preparation for that inventory, the pharmacies were directed to remove various products, including controlled substances, from their shelves that had expired or were about to expire. Kmart had entered into an agreement with Cardinal Health (Cardinal), a DEA-registered distributor, that Cardinal would pick up these products from Kmart stores, however Cardinal was unable to handle certain aspects of the Kmart returns. Cardinal was along-time customer of Respondent and made arrangements for Respondent to handle the Kmart returns of partially full containers. Ms. Dershem testified that neither Cardinal nor Kmart could predict how much material Respondent could expect.

When the investigators arrived on September 10, 1996, most of the Kmart boxes were on pallets. The boxes had labels identifying them as from Kmart, but the pallets had pieces of paper on them indicating the name of a city and a date. The investigators were told that the city names indicated locations of Cardinal facilities, and the date reflected the date that Respondent received the shipment.

According to Ms. Dershem, the Kmart facilities had been instructed to place a label on each box that identified whether it contained controlled substances. If the boxes indicated that they contained controlled substances, they were immediately taken to Respondent's controlled substance cage. The boxes were then processed in three stages. ''Stage 1'' consisted of breaking down the pallet, opening up each box, ascertaining which Kmart store was responsible for each box, and checking for a receipt document. If there was no receipt document, the Kmart store would be contacted to obtain the document. Also any Schedule II controlled substances or non-controlled substances were removed during this stage. The boxes were then resealed until ''stage 2'' processing. ''Stage 2'' processing consisted of counting the actual dosage units in the boxes and verifying that what Respondent actually received was what the receipt document listed as the contents of the box. The receipt document was then signed. During ''stage 3'' the information was entered into Respondent's computer. As the number of Kmart boxes received at Respondent increased, Respondent was unable to complete all three stages of processing upon receipt. Therefore, when the DEA investigators arrived to conduct their inspection, the Kmart boxes were in various stages of processing. The receipt documents were maintained inside the boxes during processing.

As a result, in order to conduct their accountability audit, the DEA investigators began opening each of the Kmart boxes to look at the receipt documents to ascertain whether the boxes contained any of the controlled substances being audited. In so doing, the investigators discovered that some receipt documents were missing and that others were inadequate, incomplete, incorrect, or illegible.

By the end of the first day of the inspection, the investigators had inventoried the controlled substances to be audited in all of the non-Kmart boxes. At the end of the second day, the DEA investigators still had a large number of Kmart boxes to inventory. The investigators asked Ms. Dershem to have the receipt documents pulled from the boxes and that they would not return to Respondent the next day in order to give Respondent's personnel an opportunity to pull together the documents. Ms. Dershem had the documents available for the investigators the next day. Nonetheless the DEA investigators decided to stop inventorying the Kmart boxes believing that based upon the state of the documents, it would be impossible to audit the contents of the boxes.

Consequently, DEA did not include the Kmart shipments in conducting its audit. As the initial inventory for the audit, DEA used Respondent's December 1995 biennial inventory, which consisted of a 42 page computer printout plus six handwritten pages of information not yet entered into the computer. Upon review, it was discovered that there were approximately 47 entries in the inventory for substances that were the subject of the audit.

DEA investigators noted several entries in the biennial inventory which caused them concern. First, the size of the containers was not listed on the handwritten portion of the inventory. Second, regarding Valium 10 mg./2 ml. ampules, the entry in the physical count column was a ''6,'' when in fact Respondent had 3 ampules. According to Ms. Dershem, the number of ampules (3) was multiplied by the package size (2 ml.). However, a DEA investigator testified that DEA considers an ampule a dosage unit so the entry should have been ''3'' instead of ''6.'' Third, there were errors in three entries on the handwritten pages for propoxyphene napsylate. It is undisputed that these entries referred to propoxyphene napsylate with acetaminophen, a different product. Finally, another problem regarding these propoxyphene napsylate entries is that Respondent's inventory listed the number of containers, but did not indicate the size of the containers. Therefore, there was no way to know the total quantity of the drug on hand. For purposes of the audit computations, the DEA investigators listed that each container held 100 dosage units based upon the representation of the cage supervisor.

DEA's audit revealed a shortage of 400 propoxyphene napsylate and 3 ampules of Valium injectable, however these shortages resulted from Respondent's inaccurate entries on the December 1995 inventory. There were also relatively minor discrepancies regarding four other audited substances, and the remaining four audited substances balanced. The lead DEA investigator testified at the hearing in this matter that ''[i]f I had gone in the firm and the only problem I had was these minor audit discrepancies, we would not be sitting here.'' A former DEA investigator who now works as a consultant conducted an on-site evaluation of Respondent's controlled substance handling in June 1997. The consultant conducted an audit of the same substances that DEA audited covering the same time period as DEA's audit. He testified that he found no discrepancies with respect to any of the audited substances. However, the consultant acknowledged that he did not know whether DEA was provided with the same records that he used. Also, the consultant conducted an additional accountability audit of the substances for September 1996 to June 1997, and there were no discrepancies.

As part of its September 1996 inspection, DEA reviewed Respondent's recordkeeping procedures regarding the Kmart shipments, and had concerns regarding the maintenance of the receipt

documents. The lead DEA investigator testified that these documents were not readily retrievable. The receipt documents were still in the Kmart boxes and there no copies of these documents in any receiving file. Further, not all of the boxes even contained any receipt documents and some of the documents were either incomplete or inaccurate.

It was also the investigator's opinion that these documents were not current. Ms. Dershem told the investigator that prior to the Kmart shipments receiving information was generally entered into the computer within 48 hours of receipt of a shipment. However, there were boxes that were part of the Kmart shipments that were received by Respondent in July 1996, but had not been completely processed by the September 1996 inspection. The investigator testified that because of this delay, DEA was unable to determine whether any noted discrepancies between the subsequent actual inventories of the contents of the boxes and the receipt documents generated by the shipper were due to in-transit loss or on-site diversion.

As a result of these problems, the investigator testified that DEA was unable to conduct an accountability audit that included the Kmart shipments. This concerned the investigator since the Kmart shipments amounted to the vast majority of the controlled substances for which Respondent was accountable.

However Ms. Dershem disagreed, testifying that the receiving documents were readily retrievable because they could easily have been pulled out of the boxes, as demonstrated by Respondent being able to make copies of the documents available for the investigator overnight. Also, both Mr. and Ms. Dershem stated that Respondent had always maintained the receiving documents in boxes it received from customers and had never before been told that this practice was improper or violated any regulations, nor that it needed to put copies of the documents in a receiving file.

Another concern of the DEA investigators regarding the Kmart shipments is that Respondent did not obtain any receipt documents from Cardinal. According to the DEA witnesses who testified, Cardinal was the true shipper of the controlled substances to Respondent, not Kmart. The lead investigator testified that DEA considers the supplier to be whoever shipped the controlled substances to the receiving registrant. She further testified that as far as DEA was concerned, Respondent's supplier for the Kmart shipments was Cardinal, and as a result, Cardinal should have opened the Kmart boxes upon receipt, inventoried the contents, and created an inventory document to accompany the boxes to Respondent. Another DEA investigator testified that transactions between Kmart and Cardinal and between Cardinal and Respondent were distributions, and therefore the recordkeeping requirements in 21 CFR part 1304 applied to these separate transactions.

Ms. Dershem testified that Respondent believed that Cardinal was merely acting as the freight forwarder of the boxes from Kmart to Respondent and therefore no records were needed from Cardinal. An internal Cardinal memorandum instructed Cardinal managers that ''[t]hese boxes are absolutely not to be opened or counted at our DC's, or else they will not longer meet the DEA's criteria for cross-dock shipments.'' Ms. Dershem testified that it was her understanding that Cardinal would have the responsibility of maintaining the audit trail showing how many boxes it sent to Respondent. According to Ms. Dershem, Cardinal told her that it would take care of shipping and she testified that she had no reason to question Cardinal because Cardinal is a large wholesaler with staff who specialize in regulatory compliance.

However, DEA witnesses testified that the arrangement between Kmart, Cardinal and Respondent did not qualify as freight forwarding. An investigator and former chief of the Liaison Unit in the Liaison and Policy Section of DEA's Office of Diversion Control testified that both freight forwarding and cross-dock shipping refer to a DEA-registered distributor's use of a separate unregistered warehouse, operated and controlled by the distributor, as an interim warehouse to which controlled substances are conveyed by a long-haul trucker and at which the drugs are placed in smaller, local trucks for conveyance to another registrant who is the consignee for the order. But other DEA witnesses offered slightly different definitions of the terms.

Yet, it is undisputed that at the time of the Kmart shipments, there were no regulations, nor did DEA have a formal written policy, regarding freight forwarding or cross-dock shipping. In fact, proposed regulations regarding freight forwarding were published in December 1996, and they have yet to be finalized. Nonetheless, DEA has permitted freight forwarding facilities to operate in some instances despite the lack of regulations or formal policy.

The consultant who conducted the on-site evaluation of Respondent in June 1997, not only conducted an audit of the same substances that DEA audited in September 1996, but also reviewed Respondent's recordkeeping system to determine whether it was able to prevent or detect diversion. In his opinion, Respondent's records were very orderly and met the requirements of the Controlled Substances Act and its regulations. He further testified that he did not detect any diversion occurring at Respondent.

Another consultant testified that he visited Respondent in August 1997 and found that Respondent's personnel were able to produce records promptly, that the records were very organized, easy to read, and in good order, and that he believed that Respondent's records exceeded DEA's requirements.

Ms. Dershem testified that after the September 1996 inspection, Respondent changed its procedure for handling receipt documents: ''we actually take the document, we verify the products, correct it, make a photocopy of the document, put it in a pending file, mark the box with a number, mark the packing slip with a number.'' According to Ms. Dershem, the procedure in effect at the time of the hearing before Judge Bittner included writing the number of the box on the receipt document in a pending file so that DEA investigators could ascertain whether information from the document had been entered into the computer and could match the receipt document to the appropriate box.

The Deputy Administrator must first determine whether any violations of the law and regulations have occurred since the effective date of the previous final order. The Government contends that Respondent violated 21 CFR 1304.11(a)[1], 1304.15(c) and (d), and 1304.16. These provisions essentially require that a registrant's inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and that such inventory shall include, among other things, the name of the substance, the number of dosage units in each commercial container, and the number of commercial containers.

The Deputy Administrator agrees with Judge Bittner that Respondent violated these provisions because its December 1995 biennial inventory failed to correctly identify propoxyphene napsylate with acetaminophen, failed to indicate the number of dosage units in

[1] References to the Code of Federal Regulations are to provisions in effect at the time of the September 1996 inspection.

each commercial container of propoxyphene napsylate with acetaminophen, and failed to correctly indicate the total quantity of Valium ampules. Also there were no container sizes listed on the handwritten portion of the inventory.

The Government also contends that Respondent violated 21 U.S.C. 827 and 21 CFR 1304.04(f)(2), by failing to maintain its receipt records for the Kmart shipments either separately from all other records or in such form that the information required is readily retrievable from the ordinary business records of the registrant. The Deputy Administrator agrees with Judge Bittner's rejection of Respondent's contention that its maintenance of receipt records in boxes meets the requirement of maintaining the records separate from all other records. As Judge Bittner noted, ''adopting Respondent's interpretation would mean that a registrant could scatter controlled substance records around its establishment in no particular order, a result I do not believe the regulations intended to achieve.''

The question then becomes whether Respondent's records of receipt regarding the Kmart shipments were readily retrievable. The record establishes that DEA investigators advised Respondent that the receipt documents from Respondent's customers were the primary records and that the 1993 Memorandum of Understanding entered into between DEA and Respondent required that Respondent obtain these documents from its customers. It is undisputed that to the extent that Respondent's customers provided these documents, Respondent was able to make them available to DEA investigators within a day of being asked to produce the documents. Therefore, it appears that the receipt documents from Respondent's customers were readily retrievable.

However, the Deputy Administrator finds that 21 U.S.C. 827 and 21 CFR 1304.21, require that a registrant maintain a record of its receipt of controlled substances. The Deputy Administrator agrees with Judge Bittner that the receipt documents in the Kmart boxes created by Respondent's customers are not what needed to be readily retrievable, but rather Respondent's record of what it received. Even if the receipt documents from the customers had been out of the boxes, DEA could not have conducted an accurate accountability audit because they did not reflect what controlled substances were actually received by Respondent. The Deputy Administrator agrees with Judge Bittner that, ''[t]he only meaningful document is that which shows what the customer claimed to send versus what Respondent claims to have received, and that document does not exist until Respondent's personnel inventory the contents of the boxes.'' The Deputy Administrator recognizes that DEA registrants may use invoices from their suppliers as their records of receipt, however they are not obligated to do so. As is the case with Respondent, DEA registrants may wish to verify what they receive and then create their own record of receipt. All that is required by the statute and regulations is that a registrant maintain a record of the controlled substances that it receives.

Jude Bittner concluded that Respondent's records of what it claims to have actually received were maintained and filed in chronological order and were therefore readily retrievable. As a result, Judge Bittner concluded that Respondent did not violate this provision.

The Deputy Administrator agrees with Judge Bittner that as to those records where the contents of the Kmart boxes had been inventoried and verified against the customers' receipt documents, these documents were readily retrievable. However, as to the majority of the Kmart boxes, where the contents had yet to be verified against the customers' receipt documents at the time of the September 1996 inspection, Respondent had no record of what it actually received. Consequently, the Deputy Administrator finds that all of Respondent's records of receipt were not readily retrievable, because some did not exist at the time of the September 1996 inspection.

Next, the Government contends that Respondent violated 21 U.S.C. 827 and 21 CFR 1304.21(a), by failing to maintain on a current basis a complete and accurate record of its receipt of controlled substances. Again, Judge Bittner noted that the relevant document is what Respondent indicates it actually received. ''Current'' is not defined in DEA's regulations so Judge Bittner found that ''the real question is whether Respondent processed the material and generated the verification documents sufficiently quickly.''

Judge Bittner noted that some of the Kmart boxes had been at Respondent's facility as of July 22, 1996, and had not been verified by the time of DEA's inspection in September. But, Judge Bittner found it relevant that Respondent could not predict the quantity of controlled substances it would receive or when the large shipment would be received and thus could not prepare for the shipments by hiring additional employees who would require pre-employment background checks. As a result, Judge Bittner concluded ''that the record is inadequate for a determination as to whether Respondent's records pertaining to the Kmart shipments were or were not 'current.' I therefore conclude that the Government has not met its burden of proof showing that Respondent violated this regulatory requirement.''

However, the Deputy Administrator disagrees with Judge Bittner. Respondent cannot have it both ways. Respondent does not want to be held responsible for what the customer says is in the boxes and wants the opportunity to verify the contents of the boxes and create its own record of receipt. But on the other hand, Respondent cannot get to verifying the contents of the boxes upon their receipt. The delay in verifying the contents of the boxes increases the potential for diversion, the very reason that records of receipt must be maintained on a current basis.

The Deputy Administrator recognizes that with large shipments, Respondent may have a more difficult time maintaining its records of receipt on a current basis. But, that is Respondent's responsibility in light of existing regulations. In order to comply with the regulations, Respondent might have to require that its customers give it more advance notice of large shipments and an estimate as to the size of the shipments in order for Respondent to adequately prepare to handle these shipments and meet its regulatory responsibilities. Nonetheless, the Deputy Administrator finds that Respondent failed to maintain all of its records of receipt of the Kmart shipments on a current basis.

Finally, the Government contends that Respondent violated 21 CFR 1304.23(c), which requires that a distributor keep a record of what controlled substances it receives that includes, among other things, the name of the person from whom the containers were received. The Government asserts that Respondent received the Kmart shipments from Cardinal, and that consequently, Cardinal was required to inventory the product at its premises and Respondent was required to obtain documentation of that inventory from Cardinal. Respondent contends that Cardinal was acting as a freight forwarder for the shipments and therefore no records were required from Cardinal.

Judge Bittner concluded that ''[i]t is undisputed that the Kmart boxes were handled at Cardinal facilities, that

Cardinal did not inventory the contents of the boxes, and that Respondent did not obtain inventories of the contents from Cardinal. Thus, according to a literal reading of section 1304.23(c), Respondent violated that section.

The Deputy Administrator disagrees with Judge Bittner to the extent that Respondent's violation of the regulation is not Respondent's failure to obtain inventories from Cardinal. Instead, Respondent violated this provision by failing to list Cardinal as the shipper of the controlled substances on its records of receipt. In light of existing regulations, Cardinal should have opened the boxes and created a record of what it shipped to Respondent, but any violations by Cardinal are not at issue in these proceedings. Respondent then should have created a record of what it received listing Cardinal as the shipper of the controlled substances. Therefore, the Deputy Administrator finds that Respondent violated 21 CFR 1304.23(c) by failing to list Cardinal as the shipper of the controlled substances on its records of receipt.

The Deputy Administrator concludes that Respondent did violate some provisions of the law and regulations relating to controlled substances since the effective date of the previous final order in this matter. The next question is whether such violations warrant revocation.

As a preliminary matter, the Government argued in its exceptions to Judge Bittner's opinion that in light of the wording of the then-Deputy Administrator's final order dated July 5, 1996, *any* violation since the effective date of the final order should cause the stay to be lifted and Respondent's registration revoked. However, the Deputy Administrator agrees with the then—Acting Deputy Administrator's remand of this matter when he directed Judge Bittner to make a recommendation as to whether a violation warrants the removal of the stay. Revocation is a harsh sanction and should not be taken lightly. The nature of a violation and the circumstances surrounding such a violation should be considered in determining whether revocation is warranted.

Pursuant to 21 U.S.C. 823(e) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration upon a finding that the continued registration would be inconsistent with the public interest. In determining the public interest, the Deputy Administrator must consider the following factors set forth in 21 U.S.C. 823(e):

(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 law;

(3) Prior conviction record of applicant under Federal or 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.

It is well established that these factors are to be considered in the disjunctive; the Deputy Administrator may properly rely on any one or a combination of factors, and give each factor the weight he deems appropriate. See Centrum Medical Enterprises, Inc., 58 FR 51,383 (1993).

Regarding factor one, Judge Bittner concluded that Respondent has established a number of controls to prevent the diversion of controlled substances, however as of the September 1996 inspection, Respondent was unable to generate an accurate report of what was in the cage. But, Judge Bittner also found it significant that ''Respondent operates under a variety of exogenous constraints, including lack of information as to when controlled substances will arrive at its facility and in what quantity and the requirement that it perform background checks on potential employees who would have access to controlled substances.'' Therefore, Judge Bittner concluded that, ''[i]n these circumstances, and given the unusual nature of the Kmart shipments and Respondent's care in ensuring that controlled substances are secured, * * * Respondent maintains effective controls against diversion and * * * this factor weighs in favor of Respondent's continued registration.''

The Deputy Administrator agrees with Judge Bittner to some extent. Respondent has instituted a number of procedures to help minimize the risk of diversion, however the violations discovered during the September 1996 inspection must be considered in determining whether Respondent has maintained effective controls against the diversion of controlled substances.

First, the Deputy Administrator has concluded that Respondent had several inaccurate entries on its December 1995 biennial inventory causing discrepancies in an accountability audit. In order to conduct an accountability audit, DEA must rely on the accuracy of a registrant's records, including its inventories. While ideally there should be no discrepancies in an audit, given the volume of Respondent's business and the explanations provided for the inaccurate entries, the Deputy Administrator finds that the violations relating to Respondent's biennial inventory are relatively minor. Even the lead DEA investigator characterized the problems as ''minor audit discrepancies.'' The Deputy Administrator therefore concludes that the violations relating to Respondent's inventory do not warrant revocation of Respondent's registration.

Next, the Deputy Administrator finds it significant that other than the Kmart shipments, Respondent's records of receipt appear to be in compliance with the regulations. But, the Deputy Administrator finds as discussed above, that Respondent's records relating to the Kmart shipments were not all readily retrievable or current. This is of serious concern to the Deputy Administrator since these requirements are in place to prevent the diversion of controlled substances. By not having readily retrievable records of receipt for several months after the controlled substances are received at Respondent's facility, the chances of diversion increase.

The Deputy Administrator recognizes Respondent's dilemma that it might take Respondent a long time to process large shipments, but it must nonetheless comply with the existing regulations which require that records of receipt be maintained on a current basis and be readily retrievable.

The disposer business is different from other DEA registered distributors, and regulations are needed to specifically address this type of DEA registrant. DEA's failure to finalize regulations that were proposed in August 1995 seems to support a conclusion that even DEA recognizes that this is a complex and evolving business, not like other distributors where receipt of controlled substances is easily verifiable.

Therefore, the Deputy Administrator does not find it appropriate to lift the stay of revocation at this time. However, until regulations are promulgated, Respondent must establish procedures to deal with large shipments of controlled substances and still comply with the existing regulations. As previously discussed, Respondent may need to require that its customers provide Respondent with more advance notice of large shipments and an estimate as to the size of the shipments so that Respondent can better prepare to meet its regulatory responsibilities.

Finally, the Government contends that Respondent's failure to obtain receipt documents from Cardinal

threatened the closed system of distribution and therefore increased the risk of diversion. Judge Bittner concluded that Respondent violated 21 CFR 1304.23(c) by failing to obtain records from Cardinal showing what Cardinal sent to Respondent as part of the Kmart shipments. Judge Bittner further concluded however that, ''imposing such a requirement in this type of transaction quite simply makes no sense.'' Judge Bittner contended that to require Cardinal to open boxes, inventory contents and create a record would increase the chance of diversion.

But, as noted above, the Deputy Administrator concludes that Respondent's violation of the regulations was not that it did not obtain documents from Cardinal, but rather that Respondent did not list Cardinal as the shipper of the controlled substances on its own records of receipt. While it may seem to increase the chances of diversion, the regulations currently in effect nonetheless require that Cardinal should have opened the Kmart boxes, counted the contents and created a record of what it was shipping to Respondent. But, the violations by Cardinal are not at issue in this proceeding. The Deputy Administrator finds however that Respondent should have created a record of receipt indicating that it obtained the controlled substances from Cardinal, not Kmart.

However, the record supports a finding that both Respondent and Cardinal thought that Cardinal was merely acting as a freight forwarder of the controlled substances from Kmart to Respondent and as a result, no records relating to Cardinal's involvement were required. This interpretation is not supported by the existing regulations. Under the current regulations, the shipments from Kmart to Cardinal and from Cardinal to Respondent are considered separate distributions, each requiring records of the transactions.

While Respondent's interpretation is not supported by the regulations, it is not unreasonable. DEA published proposed regulations regarding freight forwarding in December 1996 which have yet to be finalized. Despite this lack of regulations, DEA has nonetheless permitted some forms of freight forwarding to occur, thereby contributing to the industry's confusion as to what is or is not permitted as it relates to freight forwarding. Therefore, Respondent's failure to list Cardinal as the shipper of the controlled substances on its records of receipt does not warrant revocation at this time.

As to factor two, there is not evidence in the record to indicate that Respondent does not comply with applicable state and local law. Likewise, there is no evidence relating to factor three that Respondent or any of its officers or agents have ever been convicted under any Federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.

Regarding factor four, Respondent's past experience in the distribution of controlled substances appears to be good. Respondent appears to have a good system in place for tracking what controlled substances leave its facility and where they go.

Pursuant to factor five, the Deputy Administrator agrees with Judge Bittner that ''[b]oth Dershems credibly expressed their willingness to comply with DEA requirements, and * * * that Respondent has implemented and will continue to implement measures to minimize the risk of diversion of controlled substances.''

Judge Bittner concluded that even though some regulatory violations occurred, ''Respondent's management remains willing to implement additional measures as necessary to prevent diversion.'' Judge Bittner therefore recommended that the Deputy Administrator conclude that Respondent's continued registration would not be inconsistent with the public interest, and that the Deputy Administrator withdraw the final order published on July 16, 1996, revoking Respondent's registration, permit Respondent to retain its registration, and grant any pending applications for renewal of its registration.

In its exceptions to Judge Bittner's opinion, the Government argued that due to the problems with Respondent's records in the past, the parties agreed that Respondent would obtain records from shippers, and that the DEA investigators made it clear to Respondent that the records from the customers would be considered Respondent's records of receipt. However as noted above, the records from Respondent's customers would not be useful in conducting an audit because they would not necessarily reflect what controlled substances Respondent actually received. But the Deputy Administrator agrees with the Government that DEA continues to be unable to perform audits without current records of receipt. Therefore as previously discussed, Respondent needs to develop procedures to deal with large shipments and the creation of its records of receipt in a prompt manner. The Government's remaining exceptions, and the Respondent's reply to those exceptions, have already been addressed in this final order, and require no further discussion here.

The Deputy Administrator concludes that other than the minor problems with Respondent's December 1995 inventory, Respondent's regulatory violations center around the Kmart/Cardinal shipments. Respondent's non-Kmart recordkeeping practices seem to be in compliance with the regulations. Respondent's problems appear to be in dealing with large shipments of the type received by Respondent from Kmart with partial bottles and random pills in each box.

Regulations exist to protect the public health and safety and they apply to Respondent as a registered distributor of controlled substances. Even though the current regulations were not promulgated with Respondent's type of business activity in mind, Respondent must comply with the existing regulations when handling these large shipments.

However, the Deputy Administrator recognizes that Respondent continues to appear willing to do whatever it takes to comply with its regulatory responsibilities. The Deputy Administrator also acknowledges the need for regulations that address the unique aspects of the disposer industry and freight forwarding. Therefore, the Deputy Administrator concludes that it is not in the public interest to lift the stay and revoke Respondent's registration at this time.

But unlike Judge Bittner, the Deputy Administrator concludes that further monitoring of Respondent is still necessary. Respondent's failure to create records of receipt for large shipments in a prompt manner threatens the closed system of distribution of controlled substances and increases the likelihood of diversion.

Therefore, the Deputy Administrator concludes that is in the public interest to continue the stay of revocation for one year from the effective date of this final order. The Deputy Administrator orders that within one month of the effective date of this final order, Respondent shall present evidence to the DEA office in Philadelphia that it has developed procedures to deal with large shipments of controlled substances and to maintain its records of receipt on a current basis and in a readily retrievable manner. Thereafter, during the one year probationary period, DEA will conduct inspections and audits in compliance with 21 U.S.C. 880 to determine if Respondent's records of receipt are now maintained in a readily retrievable manner and on a current basis.

If DEA's inspections or audits reveal that Respondent still does not maintain its records of receipt in a readily retrievable and current manner, the Deputy Administrator will remove the stay and revoke Respondent's DEA Certificate of Registration. However, if the inspections reveal that Respondent is now maintaining its records of receipt in compliance with DEA regulations, then the Deputy Administrator will withdraw this final order and the final order published on July 16, 1996, will permit Respondent to retain its registration, and will renew the registration.

Also to avoid further confusion within the controlled substance industry and to address the concerns set forth in this final order, the Deputy Administrator directs that DEA's Office of Diversion Control finalize the regulations relating to disposers of controlled substances and relating to the freight forwarding of controlled substances.

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 that the stay of revocation of DEA Certificate of Registration RR0166113, issued to RX Returns, Inc., that is set forth in the final order dated July 5, 1996 and found at 61 FR 37,801 (July 16, 1996), be, and it hereby is, continued for one year from the effective date of this final order, subject to the above described conditions. This final order is effective October 29, 1999.

Dated September 20, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99–25357 Filed 9–28–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 23, 1999, and published in the **Federal Register** on March 5, 1999 (64 FR 10725), Sigma Aldrich Research Biochemicals, Inc., Attn: Richard Miliius, 1–3 Strathmore Road, Natick, Massachusetts 01760 made application to the Drug Enforcement Administration (DEA) by letter to be registered as a bulk manufacturer of fentanyl (9801).

A registered bulk manufacturer of fentanyl filed written comments and an objection in response to the notice of application. Review of the APA's definitions of license and licensing reveals that the granting or denial of a manufacturer's registration is a licensing action, not a rulemaking. Courts have frequently distinguished between agency licensing actions and rulemaking proceedings. *See, e.g. Gateway Transp. Co.* v. *United States*, 173 F. Supp. 822, 828 (D.C. Wis. 1959); *Underwater Exotics, Ltd.* v. *Secretary of the Interior*, 1994 U.S. Dist. LEXIS 2262 (1994). Courts have interpreted agency action relating to licensing as not falling within the APA's rulemaking provisions.

The objector argues that Sigma Aldrich Research Biochemicals, Inc. cannot prove its registration as a bulk manufacturer of fentanyl is in the public interest, that Sigma Aldrich Research Biochemicals, Inc.'s registration is not required to produce an adequate and uninterrupted supply of fentanyl, that there is sufficient competition with the present bulk manufacturers.

The arguments of the objector were considered, however, DEA has reviewed the firm's safeguards to prevent that theft and diversion of fentanyl and found that the firm has met the regulatory requirements and public interest factors of the Controlled Substances Act.

Sigma Aldrich Research Biochemicals, Inc. has been and is currently registered with DEA as a manufacturer of other Schedule II controlled substances. Sigma Aldrich Research Biochemicals, Inc.'s application is based on the firm's request to add fentanyl to its existing registration as a bulk manufacturer. The firm has been investigated by DEA on a regular basis to determine if the firm maintains effective controls against diversion and if its continued registration is consistent with the public interest. These investigations have included, in part, inspection and testing of the firm's physical security, audits of the firm's records, verification of compliance with state and local law and a review of the firm's background and history. These investigations have found Sigma Aldrich Research Biochemicals, Inc. to be in compliance with the Controlled Substances Act (C.S.A.) and its implementing regulations in recent years.

Under Title 21, Code of Federal Regulations, § 1301.43(b), DEA is not required to limit the number of manufacturers solely because a smaller number is capable of producing an adequate supply provided effective controls against diversion are maintained. DEA has determined that effective controls against diversion will be maintained by Sigma Aldrich Research Biochemicals, Inc.

After reviewing all the evidence, DEA has determined, pursuant to 21 U.S.C. 823(a), that it is consistent with the public interest to grant Sigma Aldrich Research Biochemicals, Inc.'s application to manufacture fentanyl at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 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 class of controlled substance listed above is granted.

Dated: September 16, 1999.

John H. King,

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

[FR Doc. 99–25358 Filed 9–28–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of August and September, 1999.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number of proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increased of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sale or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3)