

facility. When an air shipment came into AIT, OTC's salesman would come to the facility and break down the shipment into orders. While some would be given to AIT for re-shipment, others would be given by OTC's salesman to customers who came to AIT's dock. On May 12, 2000, the salesman was seen supervising the loading of apparent pseudoephedrine product into a rental truck, which then left the area. Thus it appeared that OTC was shipping or distributing List I chemicals from an unregistered location.

From April to June 2000, Respondent kept an organized chart of pseudoephedrine product activity. This chart included: Detailed information as to customers' identity and addresses, DEA registration numbers, dates of request, invoice numbers, types of carrier used to deliver the product, quantities of product sold, any amounts returned, OTC purchase order numbers, the customers' purchase order numbers, specific product information and the payment numbers.

With regard to customer compliance, OTC sent a packet of information to its customers containing information about reporting suspicious orders, complying with DEA regulations and restricting terms of resale. It also sent a contract to retailers selling OTC products which required implementing and educating store employees on a "maximum purchase policy" and compliance with all DEA regulations. OTC also sent a conditions of sales contract to its distributor customers, explaining its requirements for resale of pseudoephedrine and ephedrine products. A suspicious orders guide sheet was also provided both retail and distributor customers, enumerating a list of suspicious factors found in the DEA's Chemical Handler's Manual. It also explained that distributors, who were most familiar with their customers and circumstances, must use their best judgment in identifying suspicious orders. Govt. Ex. 11 at 5. With regard to OTC's customer files, most contained photographs of their facilities and photocopies of their representative's driver's license.

OTC reported suspicious transactions to DEA by letter five times between November 18, 1999, and June 22, 2000. Its predecessor, L&M Vending, also reported suspicious transactions by letter on five occasions between March and July 1999.

DEA has implemented a system of documenting and informing a company that products it has manufactured or distributed have surfaced at a site associated with clandestine drug

manufacturing. Fourteen DEA Warning Letters were addressed to Respondent between January 6, 1999, and October 18, 2000, enumerating over 20 different seizures of OTC's pseudoephedrine product at clandestine sites. These letters documented the seizure of 28,423 bottles of 60-count List I chemical product, 116 bottles of 100-count List I chemical product and 32,589 bottles of 120-count List I chemical products. During the period November 1999 to July 2000, OTC pseudoephedrine product was seized at clandestine laboratories in eight states, with over 2 million dosage units seized in Oklahoma alone.

OTC sold List I chemical products to Tobacco Wholesale. Sales increased from 110 cases in February 2000 to over 800 cases by May 2000. Larry Petit thought this was appropriate, as that firm would become OTC's regional distributor in Oklahoma. He also testified he had an agreement with another List I chemical wholesaler, Branex to be OTC's regional distributor in Florida. However, this was not a written agreement, but one orally negotiated by OTC's salesman. Petit was unaware if OTC had a special price agreement with Branex, whether he had assessed Branex's ability to compete in the Florida pseudoephedrine market or if Branex had been asked to provide OTC a list of its retail customers.

There were instances when Larry Petit also did not check on the trade references supplied by customers or know if anyone from OTC had checked on their downstream customers. Petit also admitted that he ignored references supplied by customers even though he referred to the reference as a "bad guy."

In the traditional market, Pfizer is the manufacturer and distributor of the Sudafed product line and one of the largest sellers of pseudoephedrine products in the United States. Pfizer's major customers include retail trade outlets such as drug and grocery store chains and mass merchandisers. From August 1999 to April 2000, OTC sold almost one-third the number of pseudoephedrine products sold by Pfizer nationwide. Pfizer's representative was not aware of OTC as a competitor and concluded OTC's brand was not sold in the same market as Sudafed.

The L. Perrigo Company is the largest manufacturer of over-the-counter pharmaceutical products for the "store brand" market, which are sold under various labels and compete with nationally advertised brands. From August 1999 until April 2000, OTC sold over one-third the number of tablets of pseudoephedrine product sold by

Perrigo. Perrigo's representative had never seen or heard of the OTC's product and concluded it was neither a national brand nor a competitor of Perrigo's.

During the hearing and in post-hearing filings, the Government asserted that Respondent's registration should be revoked on public interest grounds. It argued that OTC failed to maintain effective controls against diversion, that the MOA bound OTC to additional requirements with which OTC failed to comply and that OTC failed to take corrective action after being notified of possible diversion of its product. The Government also contends OTC failed to comply with relevant Federal, State and local law by failing to report a regulated transaction which included a suspicious method of payment to DEA, failure to identify the other party to a regulated transaction, failure to keep and maintain records of regulated transactions and failure to keep and maintain accurate inventory records.

The Government contends OTC's principal manager was aware of DEA regulatory requirements and knew, through DEA Warning Letters, that its pseudoephedrine product was being diverted to the illicit production of methamphetamine. The Government further argues OTC was not providing listed chemical products for the traditional and recognized therapeutic market.

Respondent contends it substantially satisfied its regulatory obligations, entered into a voluntary agreement imposing additional responsibilities, substantially followed those obligations and attempted to consult with DEA to improve its operations. It further points to Larry Petit's extensive work with the DEA. While acknowledging violation of the record-reporting provision of the MOA when it failed to provide purchase orders to DEA, it argues this violation does not justify revocation, given OTC's remedial efforts to rectify that error.

Pursuant to 21 U.S.C. 823(h) and 824(a)(4), the Acting Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal for such registration, if she determines that registrant's continued registration would be inconsistent with the public interest. Section 823(h) requires that the following factors be considered in determining the public interest:

(1) Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels.

(2) Compliance by the applicant with applicable Federal, State and local law.