

from August 1999 until April 2000. This is a sizable share compared to the sales of the two largest sellers of pharmaceutical pseudoephedrine products in the United States, Pfizer and Perrigo. Despite the "share" of the potential market that OTC's millions of tablets represented, neither the Pfizer or Perrigo representatives were even aware of OTC as a possible competitor.

Further, the government established that between January 6, 1999 and October 18, 2000, 14 Warning Letters enumerated over 20 different seizures of OTC's pseudoephedrine products from illicit sites, including 28,423 bottles of 60-count product, 116 bottles of 100-count product and 32,589 bottles of 120-count products. The Acting Deputy Administrator agrees with the Administrative Law Judge that these warning letters demonstrate the movement of OTC's List I chemical products into the illicit market, an additional factor that OTC's continued handling of these products creates a risk to the public health and safety by fueling the activities of that illicit market.

The Acting Deputy Administrator has considered the totality of the circumstances, including Respondent's favorable evidence. *Martha Hernandez, M.D.*, 62 FR 61,145, 61,147 (1997). In this regard, Larry Petit's relationship with DEA as a cooperating source; OTC's financial audit and efforts undertaken to improve the company's financial records and better monitor its billing and shipping records and invoices; OTC's willingness to take action in response to several DEA Warning Letters; its acceptable customer compliance files; and the filing of some suspicious transaction reports by OTC are all noted. The Acting Deputy Administrator has also taken into consideration OTC's prompt notification to the Dallas Field Division of its receipt of product that came into its possession inadvertently after the Order of Immediate Suspension had been served on it, a fact pointed out in Respondent's Exceptions to the Opinion and Recommended Ruling.

On the other hand, Larry Petit's experience as a cooperating source should have sensitized him to the threat of criminal activity posed by diversion of List I chemical products and the need for OTC's full compliance with both DEA regulations and the terms of its MOA. Further, while the financial audit was a positive business step, it did not focus on the more pressing need for regulatory compliance and strict record keeping actions necessary to ensure future accountability in the handling of listed chemical products.

The Acting Deputy Administrator concludes Respondent's registration with DEA would be inconsistent with the public interest. Although some positive efforts have been undertaken after initiation of these proceedings, OTC's track record has been one of non-compliance with recordkeeping requirements of List I chemical products and an inability to account for large quantities of List I chemical products. OTC further failed to fully comply with the terms of the MOA, failing to provide complete sales records, adequate inventory records or purchases records as required. Further, OTC's handling and delivery of List I chemical products at AIT's unregistered and insecure freight facility creates an unacceptable risk of diversion.

The Acting Deputy Administrator agrees with the Administrative Law Judge that DEA has insufficient assurances that Respondent, under the possible direction of Tim Petit, will be able to aggressively correct its List I chemical product handling practices and recordkeeping problems to a level that would justify its continued registration as being in the public interest. In the past, under the direction of Larry Petit, Respondent's disregard for the regulations and its obligations under the MOA make questionable its commitment and ability to comply with the DEA statutory and regulatory requirements designed to protect the public from the diversion of listed chemicals. *See, e.g., Seaside Pharmaceutical Co.*, 67 FR 12,580, 12,583 (2002); *Aseel, Incorporated, Wholesale Division*, 66 FR 35,459, 35,461 (2001).

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, 0044580RY, previously issued to OTC Distribution company, be, and it is, hereby revoked. The Acting Deputy Administrator further orders that any pending applications for renewal or modification of said registration be, and they hereby are, denied. This order is effective December 18, 2003.

Dated: November 26, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 9, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor. To obtain documentation, contact Darrin King on 202-693-4129 (this is not a toll-free number) or E-Mail: king-darrin@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Office of Disability Employment Policy (ODEP), Office of Management and Budget, Room 10235, Washington, DC 20503 (202-395-7316/this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Office of Disability Employment Policy.

Type of Review: New collection.

Title: National Survey of Sub-minimum Wage (14c) Certificate Recipients.

OMB Number: 1230-0NEW.

Affected Public: Not-for-profit institutions.

Type of Response: Reporting.

Frequency: One time.