

Dated: March 29, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Gazaly Trading; Denial of Application

On March 14, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Gazaly Trading (Gazaly) proposing to deny its application executed on November 9, 2000, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of Gazaly would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h) and 824(a). The Order to Show Cause also notified Gazaly that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to Gazaly at its proposed registered location and was received on March 24, 2003. DEA has not received a request for hearing or any other reply from Gazaly or anyone purporting to represent the company in this matter.

Therefore, the Acting Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause to the applicant's last known address, and (2) no request for hearing having been received, concludes that Gazaly has waived its hearing right. *See Aqvi Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1309.53 (c) and (d) and 1316.67 (2003). The Acting Deputy Administrator finds as follows:

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.

Phenylpropanolamine, also a list I chemical, is presently a legitimately manufactured and distributed product used to provide relief of the symptoms

resulting from irritation of the sinus, nasal and upper respiratory tract tissues, and is also used for weight control. Phenylpropanolamine is also a precursor chemical used in the illicit manufacture of methamphetamine and amphetamine. Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is an ongoing public health concern in the United States.

The Acting Deputy Administrator's review of the investigative file reveals that DEA received an application dated November 9, 2000, from Gazaly Trading located in Orlando, Florida. The application was submitted on behalf of Gazaly by its owner, Redwan Gazaly (Mr. Gazaly). Gazaly seeks DEA registration as a distributor of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. There is no evidence in the investigative file that Gazaly has sought to modify its pending registration application in any respect.

Following receipt of the above application, on December 28, 2000, DEA Diversion Investigators conducted an on-site pre-registration inspection at Gazaly's proposed registered location. During the inspection, Diversion Investigators advised Mr. Gazaly of regulatory requirements and problems surrounding the diversion of list I chemicals. The Diversion Investigators also reviewed security, recordkeeping and distribution procedures with Mr. Gazaly and provided him with appropriate materials regarding DEA requirements for handlers of listed chemicals.

During the pre-registration investigation, Mr. Gazaly informed DEA Diversion Investigators that he had no previous experience handling list I chemical products. Nevertheless, he anticipated that Gazaly's sale of those products would constitute approximately 10% of his business activity. Mr. Gazaly also further disclosed that his customers are convenience stores, gas stations, and general stores, and the purpose of obtaining a registration to distribute list I chemical was to ensure distribution of other products to his customers.

Mr. Gazaly also provided DEA a list of customers to whom listed chemical products would be sold. Upon review of the list it was learned that approximately fifteen potential customers of Gazaly were associated with criminal targets in previous DEA investigations. Several of Gazaly's potential customers were also targets of ongoing criminal cases, apparently related to unlawful handling of listed chemical products. In addition, Mr. Gazaly advised DEA Diversion

Investigators that he would only distribute list I chemicals to customers located in the State of Florida; however, further review of the customer list revealed a business establishment located outside of Florida that was also the target of a DEA criminal investigation.

Pursuant to 21 U.S.C. 823(h), the Acting Deputy Administrator may deny an application for Certificate of Registration if she determines that granting the registration would be inconsistent with the public interest as determined under that section. Section 823(h) requires the following factors be considered in determining the public interest:

(1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) Compliance with applicable Federal, State, and local law;

(3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) Any past experience in the manufacture and distribution of chemicals; and

(5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive; the Acting Deputy Administrator may rely on any one or combination of factors, and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See, e.g., Energy Outlet*, 64 FR 14269 (1999). *See also Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

The Acting Deputy Administrator finds factors four and five relevant to Gazaly's pending registration application.

With respect to factor four, the applicant's past experience in the distribution of chemicals, the Acting Deputy Administrator finds this factor relevant to Mr. Gazaly's lack of experience in the handling of list I chemical products. In prior DEA decisions, the lack of experience in the handling list I chemicals was a factor in a determination to deny a pending application for DEA registration. *See, Matthew D. Graham*, 67 FR 10229 (2002); *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002). Therefore, this factor similarly weighs against the granting of Gazaly's pending application.

With respect to factor five, other factors relevant to and consistent with

the public safety, the Acting Deputy Administrator finds this factor relevant to Gazaly's proposal to distribute listed chemical products primarily to convenience stores and gas stations. While there are no specific prohibitions under the Controlled Substance Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found that business establishments such as gas stations and convenience stores constitute sources for the diversion of listed chemical products. *See, e.g., Sinbad Distributing*, 67 FR 10232, 10233 (2002); *K.V.M. Enterprises*, 67 FR 70968 (2002) (denial of application based in part upon information developed by DEA that the applicant proposed to sell listed chemicals to gas stations, and the fact that these establishments in turn have sold listed chemical products to individuals engaged in the illicit manufacture of methamphetamine); *Xtreme Enterprises, Inc., supra*.

Factor five is also relevant to Gazaly's proposal to distribute to potential customers under criminal investigation, or to customers associated with firms that were the subject of criminal investigations. The conduct of a potential customer has been deemed a relevant consideration under factor five. *Shani Distributors*, 68 FR 62324, 62326 (2003).

As noted above, there is no evidence in the investigative file that Gazaly ever sought to modify its pending application with regard to listed chemical products it seeks to distribute. Among the listed chemical products that the firm seeks to distribute is phenylpropanolamine. In light of this development, the Acting Deputy Administrator also finds factor five relevant to Gazaly's request to distribute phenylpropanolamine, and the apparent lack of safety associated with the use that product. DEA has previously determined that an applicant's request to distribute phenylpropanolamine constitutes a ground under factor five for denial of an application for registration. *Shani Distributors, supra*. Based on the foregoing, the Acting Deputy Administrator concludes that granting the pending application of Gazaly would be inconsistent with the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by Gazaly Trading be, and it hereby is, denied. This order is effective May 26, 2004.

Dated: March 29, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03-41]

Alton E. Ingram, Jr., M.D.; Revocation of Registration

On June 25, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Alton E. Ingram, Jr., M.D. (Respondent) of Pensacola, Florida, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, BI3210642, as a practitioner, pursuant to 21 U.S.C. 824(a)(3) and deny any pending applications for renewal of that registration pursuant to 21 U.S.C. 832(f). As a basis for revocation, the Order to Show Cause alleged that Respondent's license to practice medicine in Florida had been indefinitely suspended and accordingly, he was not authorized to handle controlled substances in Florida, the State in which he is registered.

On August 6, 2003, Respondent, acting *pro se*, timely requested a hearing in this matter. On August 22, 2003, Administrative Law Judge Gail A. Randall (Judge Randall) issued the Government, as well as Respondent, an Order for Prehearing Statements.

In lieu of filing a prehearing statement, the Government filed Government's Request for Stay of Proceedings and Motion for Summary Disposition. The Government argued Respondent was without authorization to handle controlled substances in the State of Florida and, as a result, further proceedings in the matter were not required. Attached to the Government's motion was a copy of the State of Florida, Department of Health's Order of Emergency Suspension of License, indefinitely suspending Respondent's license to practice medicine in Florida, effective as of September 11, 2002.

On September 3, 2003, Judge Randall issued an Order and Notice providing Respondent an opportunity to respond to the Government's motion. Respondent filed a timely response, which included a concession that his authority to prescribe controlled substances in the State of Florida was then currently, albeit temporarily, suspended. Based on other issues raised

in that response, Judge Randall ordered the Government to file an amendment to its Motion for Summary Disposition, which it did on October 10, 2003. Subsequently, the Government filed its October 14, 2003, Motion to Rescind Amended Motion for Summary Disposition (first amended motion), requesting that its accompanying Second Amended Motion for Summary Disposition be considered in lieu of the first amended motion. Judge Randall denied the motion to rescind the first amended motion as it was then a part of the administrative record. However, she accepted the Second Amended Motion for Summary Disposition for consideration on the merits.

On November 7, 2003, Judge Randall issued her Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Randall granted the Government's Motion for Summary Disposition, finding Respondent lacked authorization to handle controlled substances in Florida, the jurisdiction in which he is registered. Judge Randall recommended that Respondent's DEA registration be revoked and any pending applications for renewal or modification of that registration be denied. No exceptions were filed by either party to Judge Randall's Opinion and Recommended Decision and on December 15, 2003, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds that Respondent holds DEA Certificate of Registration, BI3210642, which expired on November 30, 2003, after initiation of these proceedings. The Deputy Administrator further finds that, effective as of September 11, 2002, the State of Florida, Department of Health issued its Order of Emergency Suspension of License, suspending respondent's authority to practice as a physician in the State of Florida. There is no evidence in the record indicating that this suspension has been stayed or that Respondent's license has been reinstated. As a result, he is not currently authorized to prescribe, dispense, administer, or otherwise handle controlled substances in the