

(3) Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law.

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

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

These factors are to be considered in the disjunctive; the Acting Deputy Administrator may rely on any one or a 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 *Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

As a preliminary matter, the Administrative Law Judge refused the Government's request to take official notice that "no business entity, intended to be a going concern, operates in such a fashion as OTC did." The Acting Deputy Administrator agrees that the broad assertion of OTC's illegitimacy as an on-going business entity embodied in this particular request is not appropriate for official notice. However, the Acting Deputy Administrator disagrees with the Administrative Law Judge's broad conclusion that DEA possesses "no specialized knowledge pertaining to general business practices of legitimate business entities" (ALJ Decision at 47). The DEA does possess special expertise in many areas of business operations, both legitimate and illegitimate, which relate to the manufacture and distribution of controlled substances and List I chemicals.

Nevertheless, deciding whether or not "any" business entity, intending to be an ongoing concern, would operate as OTC did, does require a qualitative analysis of the evidence in the particular record on a finding which could materially impact the outcome. The request also does not involve an "obvious and notorious" fact (See Attorney General's Manual at 79), is open to dispute and is not capable of ready and certain verification. Considering the foregoing and the scope of the request, the Acting Deputy Administrator will not take official notice of the specific fact which was requested.

Nevertheless, certain facts established in the record do indicate numerous deviations from what would be considered sound business practices of companies engaged in distributing regulated chemicals. As did the Administrative Law Judge, these facts

will be considered by the Acting Deputy Administrator in determining the public interest in OTC's continued registration.

The Acting Deputy Administrator also agrees with the Administrative Law Judge that OTC Distribution Company's Certificate of Registration was not terminated as a matter of law when, after initiation of these proceedings, Tim Petit filed Articles of Incorporation with the State of Texas in the name of "OTC Distribution, Inc." Ambiguity as to the Respondent's intent to alter its status as a sole proprietorship to that of corporation and to use a renewed certificate to carry out its business, was generated by conflicting notations on the December 22, 2000, application for renewal of registration signed by Tim Petit.

However, no requests for a modification to change the registrant's name or transfer the certificate of registration to a new corporate entity were ever submitted. The Government also did not introduce evidence of conduct by OTC Distribution Co., consistent with a conclusion that OTC Distribution Co. had ceased existence or discontinued business. Neither was any Texas law offered to support the conclusion that, by operation of law, OTC Distribution Co. ceased legal existence or discontinued business, simply upon filing of the articles of incorporation. Accordingly, the Acting Deputy Administrator agrees with the Administrative Law Judge that OTC Distribution Company's DEA Certificate of Registration remains a viable, if temporarily suspended, registration whose fate cannot be decided by summary disposition.

With respect to factor one, maintenance of effective controls against diversion, the Acting Deputy Administrator agrees with the Administrative Law Judge that Respondent's physical storage facility met or exceeded minimum security requirements. However, while physical security is a focus of 21 CFR 1309.71 (2000), the Acting Deputy Administrator agrees with the Government's exception to the Opinion and Recommended Ruling, that the Administrative Law Judge's discussion on this factor was unnecessarily limited to the adequacy of storage and physical access to Respondent's List I chemical products.

Among the factors required to be considered by the Acting Deputy Administrator under the general security requirements of 21 CFR 1309.71, is "[t]he adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution and disposition of List I chemicals in its operations." 21 CFR 1309.71(b)(8).

Further, prior agency rulings have applied a more expansive view of factor one than mere physical security. See, e.g., *Alfred Khalily, Inc.*, 64 FR 31,289, 31,292 (1999) and *NVE Pharmaceuticals, Inc.*, 64 FR 59,215, 59,217-18 (1999) (failure to identify a party to a transaction or engaging in transactions with non-registered entities fell under factor one); *State Petroleum, Inc.*, 67 FR 9,994, 9,994 (2002); *Hadid International, Inc.*, 67 FR 10,230, 10,231 (2002) and *Aqui Enterprises*, 67 FR 12,576, 12,578 (2002) (recordkeeping inadequate to track sales and customers within factor one).

Respondent's failure to maintain adequate administrative records and controls to permit a more precise audit of its List I chemical products, its inability or unwillingness to fully comply with its record keeping and report obligations under the MOA, its distribution of List I chemical products directly to customers from a freight facility loading dock and substantial seizures of OTC pseudoephedrine products from illicit sites, all weigh against Respondent as to factor one.

With regard to factor two, compliance with applicable law, the Acting Deputy Administrator agrees with the Administrative Law Judge that OTC was bound to comply with the provisions of the MOA, in addition to the recordkeeping, reporting and identification requirements in the Code of Federal Regulations. OTC then failed to provide the DEA with adequate inventory records, complete sales invoices or with any purchase records.

With regard to the accountability audits conducted by DEA Diversion Investigators which resulted in their finding of overages and shortages of listed chemicals, Respondent has filed exceptions to the Opinion and Recommended Ruling of the Administrative Law Judge. OTC argues the audits were not undertaken in a "manner that lends credibility to their results" and "were based on erroneous assumptions." Respondent's Exceptions at 4. However, the inability of DEA personnel to precisely account for the receipt and distribution of OTC's List I chemical products was principally attributable to Respondent's failure to maintain adequate records. The Acting Deputy Administrator is particularly troubled that Respondent was placed on notice by the terms of the MOA as to its need to maintain accountability for the List I chemicals it distributed—through its own records—and nevertheless failed to fully comply with those requirements either by intent, ignorance or neglect.

There was a substantial deviation between the results of two investigators