

proposed registered address, and (2) no request for hearing having been received, concludes that Callahan's has waived its hearing right. See *Aqui Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Acting Administrator now enters his final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67 (2003). The Acting 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.

Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a growing problem in the United States.

The Acting Administrator's review of the investigative file reveals that on May 21, 1997, DEA's Chemical Operations Registration section received an application dated May 13, 1997, on behalf of Callahan's. The application was submitted by the company's owner, Tony L. Callahan. The applicant sought DEA registration as a distributor of the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine. Because Callahan's submitted its application for registration on or before July 12, 1997, the firm qualified for temporary exemption from the requirement of registration, pursuant to 21 CFR 1309.10.

For reasons unknown, Callahan's registration application was not received by the DEA Richmond (Virginia) District Office for follow-up investigation until April 4, 1999. Nevertheless, on six separate occasions between April 27, 1999 and June 10, 1999, a DEA Diversion Investigator attempted to reach Tony Callahan by telephone to discuss information necessary for completion of the application process. There is no information in the investigative file demonstrating that DEA personnel were successful in reaching Tony Callahan during that time period. However, on December 3, 1999, and again on May 15, 2000, a DEA Diversion Investigator contacted Tony Callahan, and requested the following information:

- a. A list of the company's officers;
- b. A brief description of the company's main business;
- c. Percentage of the company's business pertaining to list I chemicals;
- d. A list of list I chemical suppliers;

- e. A list of list I chemical customers;
- f. Copies of relevant licenses; and
- g. Description of the company's security as well as a copy of any security contracts.

Callahan's failed to provide the requested information. In response, a DEA Diversion Investigator traveled to Callahan's on January 4, and March 2, 2000, again requesting information necessary to process the company's registration application. On both occasions, the investigator met with Robert Callahan (son of Tony Callahan) and his wife Lisa. Robert and Lisa Callahan were part of the management structure and provided assistance to Tony Callahan in the operation of Callahan's. Despite DEA's repeated requests, the requested information was not provided.

On February 2, 2001, the DEA Richmond office directed a letter to Tony Callahan. The letter recited DEA's repeated attempts to obtain information from Callahan's and again requested information needed to process its pending DEA application. The letter further informed Tony Callahan that pursuant to 21 CFR 1309.35, DEA "may require an applicant to submit documents of written statements of fact" relevant to process a pending application. The letter further stated that "[t]he failure of the applicant to provide such documents or statements within a reasonable time after [such request] shall be deemed a waiver by the applicant of an opportunity to present \* \* \* documents or facts for consideration by DEA in granting the application." The letter concluded that should the company fail to respond to DEA correspondence, such failure would be deemed a withdrawal of Callahan's pending application, pursuant to 21 CFR 1309.36(b). Callahan's was given thirty days to respond to DEA's letter. A similar letter was subsequently sent to Callahan's on April 16, 2001.

On or about March 5, 2001, Tony Callahan telephoned the DEA Richmond office and stated that he had sent the requested documents to DEA. However, DEA records did not show receipt of the requested information. Tony Callahan assured DEA personnel that he would send the documents.

On April 20, 2001, Tony Callahan called the Diversion Group Supervisor of the DEA Richmond Office stating that he wished to continue the registration process and to that end, again informed DEA personnel that he would submit all necessary documents. However, when DEA personnel finally received documents from Tony Callahan on May 3, 2001, the information contained

therein was found to be incomplete with respect to names, addresses, phone numbers, and DEA registration numbers of both suppliers and customers of Callahan's Foods. During the following two months, DEA's repeated attempts to obtain further information from Callahan's, and/or arrange times for on-site inspections of the business were unsuccessful.

Pursuant to 21 U.S.C. 823(h), the Acting Administrator may deny an application for Certificate of Registration if he 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 Administrator may rely on any one or combination of factors, and may give each factor the weight he 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 *Harry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

The Acting Administrator finds factors one, four, and five relevant to Callahan's Foods' pending application.

With respect to factor one, maintenance of effective controls against the diversion of listed chemicals, the Acting Administrator's review of the investigative file reveals that Callahan's Foods failed to provide to DEA information regarding security or any security contracts that the company had entered into. Therefore, the record before the Acting Administrator contains no information as to any security measures employed by Callahan's designed to prevent the diversion of listed chemicals.

Regarding factor four, the applicant's past experience in the distribution of chemicals, DEA's investigation revealed