

Title: Certification Summary Form, Reporting Summary Form for Acreage Limitation, 43 CFR part 426 and 43 CFR part 428.

Abstract: These forms are to be used by district offices to summarize individual landholder (direct or indirect landowner or lessee) and farm operator certification and reporting forms as required by the RRA, 43 CFR part 426, and 43 CFR part 428. This information allows us to establish water user compliance with Federal reclamation law.

Changes to the RRA forms and the instructions to those forms. The changes

made to the current Form 7-21SUMM-C, Form 7-21SUMM-R, and the corresponding instructions clarify the completion instructions for these forms (for example, adding verbiage to clarify when requested acreages are to be provided on a westwide or district-specific basis). Other changes to the forms and the corresponding instructions are editorial in nature and are designed to assist the respondents by increasing their understanding of the forms, and clarifying the instructions for use when completing the forms. The

proposed revisions to the RRA forms will be effective in the 2008 water year.

Frequency: Annually.

Respondents: Contracting entities that are subject to the acreage limitation provisions of Federal reclamation law.

Estimated Total Number of Respondents: 225.

Estimated Number of Responses per Respondent: 1.25.

Estimated Total Number of Annual Responses: 281.

Estimated Total Annual Burden on Respondents: 11,240 hours.

Estimate of Burden for Each Form:

Form No.	Burden estimate per form (in hours)	Number of respondents	Annual number of responses	Annual burden on respondents (in hours)
7-21SUMM-C and associated tabulation sheets	40	188	235	9,400
7-21SUMM-R and associated tabulation sheets	40	37	46	1,840
Totals		225	281	11,240

Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical use;

(b) The accuracy of our burden estimate for the proposed collection of information;

(c) Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

We will summarize all comments received regarding this notice. We will publish that summary in the **Federal Register** when the information collection request is submitted to OMB for review and approval.

Before including your address, telephone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 29, 2007.

Roseann Gonzales,

Director, Office of Program and Policy Services, Denver Office.

[FR Doc. E7-3847 Filed 3-5-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 11, 2006, and published in the **Federal Register** on October 18, 2006, (71 FR 61511), Varian, Inc., Lake Forest, 25200 Commercentre Drive, Lake Forest, California 92630-8810, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexane-carbonitrile (8603)	II
Benzoylcegonine (9180)	II

The company plans to manufacture small quantities of the listed controlled substances for use in diagnostic products.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Varian, Inc., Lake Forest to manufacture

the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Varian, Inc., Lake Forest to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: February 26, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7-3919 Filed 3-5-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ATF Fitness Products, Inc.; Denial of Application

On February 6, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to ATF Fitness Products, Inc. (Respondent) of Oakmont, Pa. The Show Cause Order proposed to deny Respondent's pending application for

registration as a distributor of the list I chemical ephedrine, on the ground that its registration would be inconsistent with the public interest. Show Cause Order at 1.

The Show Cause order alleged that ephedrine is a precursor chemical that is "commonly diverted" for use in the manufacture of methamphetamine, a Schedule II controlled substance *Id.* The Show Cause Order specifically alleged that Respondent was proposing to distribute combination ephedrine products to gyms, fitness shops, and dietary supplement dealers, and that only a very small amount of the legitimate commerce in these products occurs in such smaller retail establishments. *Id.* at 2. The Show Cause Order alleged that many smaller or non-traditional retailers of combination ephedrine products "purchase inordinate amounts of these products and become conduits for the diversion of listed chemical[s] into illicit drug manufacturing." *Id.*

Relatedly, the Show Cause Order alleged that "[t]here is no legitimate therapeutic market for this type of product" at the type of stores Respondent "propose[s] to supply," and that Respondent would be "fueling the diversion of precursor chemicals into the illicit manufacture of methamphetamine." *Id.* at 3. The Show Cause Order also alleged that in conducting verifications of Respondent's proposed customers, DEA investigators were unable to determine whether some of the proposed customers intended to buy ephedrine products from it. *Id.* at 2.

Finally, the Show Cause Order alleged that in October 2004, the Food and Drug Administration conducted an inspection of Respondent. *Id.* at 2. The Show Cause Order alleged that during the inspection, FDA investigators found quantities of ephedra, a banned product.

The Show Cause Order, which also informed Respondent of its right to a hearing, was served by certified mail, return receipt requested. On February 13, 2006, Respondent received the Show Cause Order as evidenced by the signed return receipt card. Since that time, neither Respondent, nor anyone purporting to represent it, has responded. Because (1) more than thirty days have passed since Respondent's receipt of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived its right to a hearing. See 21 CFR 1309.53(c). I therefore enter this final order without a hearing based on relevant material found in the investigative file and make the following findings.

Findings

Ephedrine is a list I chemical that, while having a therapeutic use, is easily extracted from lawful products and used in the illicit manufacture of methamphetamine, a schedule II controlled substance. See 21 U.S.C. 802(34); 21 CFR 1308.12(d). As noted in numerous DEA orders, methamphetamine is an extremely potent and addictive central nervous system stimulant. See *T. Young Associates, Inc.*, 71 FR 60567 (2006). The illegal manufacture and abuse of methamphetamine pose a grave threat to this country. Methamphetamine abuse has destroyed numerous lives and families and has ravaged communities. Moreover, because of the toxic nature of the chemicals used in producing the drug, illicit methamphetamine laboratories cause serious environmental harms. *Id.*

Respondent is a Pennsylvania corporation which is located at 140 Pennsylvania Avenue, Oakmont, Pa. Respondent's founder and president is Mr. James Vercellotti.

Respondent previously held a DEA Certificate of Registration to distribute list I chemicals. The registration, however, expired on June 30, 2001. On September 5, 2001, two DEA Diversion Investigators (DIs) conducted a regulatory investigation at Respondent's Oakmont facility. On that date, Respondent's chief financial officer told the DIs that Respondent had submitted a renewal application.

During the visit, William Charlesworth, Respondent's vice president, informed the DIs that Respondent had previously purchased bulk ephedrine powder and manufactured a combination ephedrine product, Sci-Fit Ephedrine HCL, for Asthma Relief. Respondent's officials further maintained that they were under the assumption that their distributor's registration authorized them to engage in manufacturing. The DIs subsequently advised an official of Respondent that while a manufacturer's registration authorizes its holder to distribute, a distributor's registration does not authorize its holder to manufacture.

On September 8, 2001, Mr. Charlesworth telephoned one of the DIs and informed him that Respondent was withdrawing its renewal application in part because list I products comprised less than one percent of its sales. Respondent subsequently submitted a letter to DEA withdrawing its application.

On May 5, 2004, Respondent submitted a new application for a registration to distribute ephedrine. On

September 28, 2004, two DIs returned to Respondent's facility to conduct a pre-registration investigation and met again with its president. Respondent's president told the DIs that it was a wholesale distributor of over-the-counter fitness products including food supplements and that it had customers nationwide including GNC, a chain of nutritional supplement retailers, and Walgreens, a chain of pharmacies. Respondent's president also told the DIs that the firm had been in business for fourteen years and that it expected that list I products would provide less than two percent of its sales.

Respondent provided the DIs with a list of fifty potential list I customers. Subsequently, a DI contacted ten of Respondent's customers. Seven of the stores stated that they did not plan to purchase ephedrine products; only two of the stores indicated that they would purchase the products from Respondent. Respondent's president further stated that it would require its List I customers to provide complete identification information prior to selling the products to them and that its sales manager would verify the existence of each business and its need for the products.

Following the on-site inspection, DEA was notified that the Food and Drug Administration (FDA) had conducted an inspection of Respondent's facility. During the inspection, FDA found that Respondent had in its possession approximately \$13,500 worth of products, which either contained MaHuang Extract, a source of ephedrine alkaloids, or claimed to when they did not. Eight months earlier, FDA had issued a final rule banning these products on the ground that they are adulterated and present an unreasonable risk of illness or injury under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FDA Act), 21 U.S.C. 342(f)(1)(A). See 69 FR 6788 (2004). The FDA's ban became effective on April 12, 2004.

According to the FDA, Respondent's officials asserted that they intended to export the product. Respondent's officials could not, however, provide the documentation required to demonstrate its compliance with section 801(e)(1) of the FDA Act, 21 U.S.C. 381(e)(1). FDA officials also concluded that some of the products were mislabeled in violation of federal law because they claimed to contain ingredients that were not actually present. On February 25, 2005, the U.S. Attorney's Office for the Western District of Pennsylvania filed a complaint for forfeiture of the products and U.S. Marshals seized them.

Subsequently, the FDA found that Respondent had in its possession

another product (Lipodrene), which also contained ephedrine alkaloids. On January 12, 2006, the U.S. Attorney's Office filed an additional complaint which sought the forfeiture of these products. U.S. Marshalls seized these products, which were valued at approximately \$ 16,000.

Discussion

Under 21 U.S.C. 823(h), an applicant to distribute List I chemicals is entitled to be registered unless the registration would be "inconsistent with the public interest." In making this determination, Congress directed that I consider the following factors:

- (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;
- (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.

Id.

"These factors are considered in the disjunctive." *Joy's Ideas*, 70 FR 33195, 33197 (2005). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for registration should be denied. *See, e.g., David M. Starr*, 71 FR 39367 (2006); *Energy Outlet*, 64 FR 14269 (1999). Moreover, I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

Here, I conclude that an analysis of each factor is unnecessary and that Respondent's application should be denied based on Factor Two, its record of non-compliance with applicable laws.

As recognized in numerous final orders, the illicit manufacture and abuse of methamphetamine have had pernicious effects on families and communities throughout the nation. Preventing the diversion of list I chemicals into the illicit manufacture of methamphetamine is of critical importance in protecting the public from the devastation wreaked by this drug.

While the investigative file in this case contains no evidence establishing

the risk of diversion by establishments such as those which Respondent proposed to distribute its products to, the firm's record of non-compliance with other federal laws does not inspire confidence in its willingness to faithfully obey DEA regulations. Here, the investigative file establishes two separate instances in which Respondent violated the FDA Act. Moreover, FDA found these violations well after the rule banning ephedrine alkaloids went into effect.

In section 303(h) of the CSA, Congress broadly directed that the Attorney General consider "compliance by the applicant with applicable Federal, State, and local law," 21 U.S.C. 823(h)(2), in determining whether to grant a list I distributor's registration. In contrast to the provision applicable to a practitioner's registration, Congress did not limit the subject matter of the laws that are properly considered in determining whether an applicant's compliance record supports granting it a registration. *Cf. id.* § 823(f)(4) (directing consideration of a practitioner's "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances").

Moreover, Respondent's apparent willingness to sell products which have been banned (as evidenced by the fact that banned products were found not once, but twice at its facility) and/or its inability to properly document its compliance with the FDA act (with respect to its assertion that it intended to export the products found in the first incident), are sufficiently probative of the manner in which it would likely fulfill its obligations as a registrant under the Controlled Substances Act.¹ I thus conclude that granting it a registration would "be inconsistent with the public interest." *Id.* § 823(h).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h), and 28 CFR 0.100(b) & 0.104, I order that the application of Respondent ATF Fitness Products, Inc., for a DEA Certificate of Registration as a distributor of list I chemicals be, and it hereby is, denied. This order is effective April 5, 2007.

Dated: February 23, 2007.

Michele M. Leonhart,

Deputy Administrator.

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¹ The CSA imposes extensive recordkeeping requirements on List I chemical distributors. See 21 CFR Pt. 1310.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Georgia Convenience Wholesale, Inc.; Denial of Application

On February 6, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Georgia Convenience Wholesale, Inc., (Respondent) of Doraville, Georgia. The Show Cause Order proposed to deny Respondent's pending application for a Certificate of Registration to distribute list I chemicals on the ground that its registration "would be inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 823(h)).

The Show Cause Order specifically alleged that on April 19, 2005, Respondent applied for a registration to distribute list I chemicals including pseudoephedrine, ephedrine and phenylpropanolamine (PPA), and that these products "are commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance." Show Cause Order at 1-2. The Show Cause Order alleged that Respondent was proposing to distribute these products to convenience stores, and that "law enforcement officials have observed that an overwhelming proportion of precursors found at illicit methamphetamine sites have involved non-traditional pseudoephedrine and ephedrine brands sold through convenience stores." *Id.* at 2. The Show Cause Order also alleged that as non-traditional products "become more tightly regulated, even traditional products are subject to diversion." *Id.*

The Show Cause Order further alleged that during a pre-registration investigation, Respondent's owner/operator was not aware that PPA had been withdrawn from the over-the-counter market. *Id.* Relatedly, the Show Cause Order alleged that Respondent had also sought registration for other list I chemicals even though these chemicals "were not ingredients in any over-the-counter drug product." *Id.* Finally, the Show Cause Order alleged that Respondent "does not have adequate experience or familiarity with products and the sales potentials in the industry to carry out the responsibilities of a registrant and prevent the diversion of listed chemical precursors into illicit activities." *Id.* at 3.

On or about February 24, 2006, the Show Cause Order, which also notified Respondent of its right to request a hearing, was served by certified mail,