such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as authorized by'' the CSA or the Controlled Substances Import Export Act. In addition, Respondent's conduct violated various provisions of state law. *See* Tex. Health & Safety Code 481.115(a) and 481.121(b)(5). Thus, the evidence with respect to factors two and four provides ample reason to deny Applicant's application.[3]

Factor Five—Such Other Conduct Which May Threaten the Public Health and Safety

As found above, during the consensual search of Applicant's vehicle, a Texas Highway Patrol Officer found several home-made pipes, and upon being questioned as to what he used them for, Applicant admitted that he smoked crack cocaine. Also, Applicant admitted to DEA Investigators that he had previously abused crack cocaine. While Applicant later claimed that he had stopped using crack after suffering a heart attack, he also stated that he never underwent drug rehabilitation treatment.

DEA has ''long held that a practitioner's self-abuse of a controlled substance can be considered under Factor Five even if there is no evidence that [he] abused his prescription-writing authority or otherwise engaged in an unlawful distribution to others.'' *See Scott D. Fedosky,* 76 FR 71375, 71378 (2011). *See also Tony T. Bui,* 75 FR 49979, 49989–90 (2010) (collecting cases); *David E. Trawick,* 53 FR 5326, 5327 (1988). Thus, even if there was no other evidence of misconduct on the part of Applicant, his self-abuse of crack cocaine would by, itself, constitute conduct which threatens public health and safety and renders his proposed registration ''inconsistent with the public interest.'' *Id.* 823(f).

Conclusion

Based on Applicant's misconduct in issuing prescriptions without the requisite state authority, *see* 21 CFR 1306.03(a), his admitted transportation of marijuana for a drug trafficking organization, *see* 21 U.S.C. 841(a)(1), and his self-abuse of crack cocaine, I conclude that Applicant's registration would be ''inconsistent with the public interest.'' *Id.* 823(f). Accordingly, his application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Bill Alexander, M.D., for a DEA Certificate of Registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: June 2, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012–14316 Filed 6–11–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–51]

4 OTC, Inc.; Decision and Order

On September 22, 2011, Administrative Law Judge (ALJ) Gail A. Randall issued the attached Recommended Decision. Therein, the ALJ recommended that I deny Respondent's application for a Certificate of Registration as an importer of ephedrine, a list I chemical. Neither party filed exceptions to the decision.[1]

Having considered the record as a whole, including the parties' briefs, I have decided to adopt the ALJ's findings of fact and conclusions of law except as explained below. Because I agree with the ALJ's conclusion that Respondent has failed to prove that the proposed importation of its combination ephedrine products is ''necessary to provide for medical, scientific, or other legitimate purposes'' and thus, it is not entitled to the issuance of a rule under 21 U.S.C. 952(a)(1) authorizing the importation of such products, this alone is reason to adopt the ALJ's recommendation. ALJ at 54–57. I further agree with the ALJ's ultimate conclusion that Respondent's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 958(c)(2)(A); ALJ at 80–81. Accordingly, Respondent's application will be denied.

The Section 952 Analysis

As the ALJ noted, in 2006, Congress enacted the Combat Methamphetamine Epidemic Act of 2005 (CMEA), Public Law 109–177, 120 Stat. 256. Among the CMEA's provisions was section 715, 120 Stat. 264–65, which amended 21 U.S.C. 952(a) by adding the listed chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to those substances (*i.e.,* narcotic raw materials and coca leaves) for which importation is not authorized unless the Attorney General finds the amount ''to be necessary to provide for medical, scientific, or other legitimate purposes.'' 21 U.S.C. 952(a)(1). Upon such a finding, the controlled substance or listed chemical ''may be so imported under such regulations as the Attorney General shall prescribe.'' *Id.* 952(a).

In multiple cases involving applications for a registration to import a substance subject to section 952(a)(1), DEA has held that an applicant ''cannot be registered as an importer of [such substance] unless the [Agency] finds that [it] will be allowed to import [the substance] pursuant to 21 U.S.C. 952(a)(1).'' *Johnson Matthey, Inc.,* 67 FR 39041, 39042 (2002); *see also Chattem Chemicals, Inc.,* 71 FR 9834, 9835 (2006); *Penick Corp., Inc.,* 68 FR 6947, 6948 (2003). As previously explained, a finding that the proposed importation complies with section 952(a) is ''a prerequisite to [an applicant's] registration as an importer'' of a substance subject to this provision. *Roxane Laboratories, Inc.,* 63 FR 55891, 55892 (1998). Moreover, it is settled that because the applicant is the proponent of the rule authorizing a proposed importation of a substance subject to section 952(a)(1), ''it must establish by a preponderance of the evidence that such a rule can be issued.'' *Johnson Matthey,* 67 FR at 39042; *see also Chattem,* 71 FR at 9835; *Penick,* 68 FR at 6948.

As the ALJ concluded, Respondent failed to establish by a preponderance of the evidence that its proposed importation of its combination ephedrine/guaifenesin product is ''necessary to provide for medical, scientific, or other legitimate purposes.''

[3] As evidence of his likely non-compliance with applicable laws related to controlled substances, I note that during his interviews with DEA Investigators regarding the purpose of his proposed registration, Applicant stated that he wanted to open a pain clinic ''only because he wanted to make money, and that he would do anything to make money.'' *Id.* at 2. Moreover, Applicant expressed the view that pain clinics were good because they served individuals who were addicted to pain medication without ''bogging down other clinics asking for pain pills.'' GX 7, at 3. Subsequently, Applicant stated ''what do you think pain management clinics are for? They give addicts their prescriptions because other doctors won't do it!'' *Id.* at 3–4. Putting aside the misconduct proven on this record, Applicant's comments do not inspire confidence that he would comply with federal requirements such as 21 CFR 1306.04(a), which requires that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

[1] The ALJ initially issued a decision on July 22, 2011, to which both parties filed exceptions. However, after the record was forwarded to this Office, the ALJ requested that the record be returned. Subsequently, the ALJ re-issued her decision. Neither party filed exceptions to this decision. However, I have considered the exceptions which the parties submitted following the ALJ's issuance of her first opinion.

All citations to the ALJ's decision are to the slip opinion as originally issued by her which includes a cover page and table of contents.

ALJ at 56–57. Indeed, Respondent offered no evidence that importation of its combination product is necessary to provide for any legitimate purpose.

In its post-hearing brief, Respondent asserts that its ''product will be strictly marketed for bronchial and asthma related conditions as per the Food and Drug Administration [FDA] monograph for over-the-counter bronchodilator drugs'' and that ''[t]he FDA monograph allows for the use of ephedrine for bronchial and asthma related conditions.'' Resp. Proposed Findings of Fact, Conclusions of Law, and Argument, at 1 & nn.1–2 (citing Cold, Cough, Allergy, Bronchodilator Products, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Final Monograph for OTC Bronchodilator Products, 51 FR 35,326 (1986) (codified at 21 CFR part 341)). Respondent further asserts that ''[t]here exists a strong market for [its] ephedrine product, allowing asthma suffers [sic] an option to obtain relief without having to obtain a prescription. Individuals without medical insurance or the ability to visit a physician immediately will be able to obtain cost-effective relief from the comfort of their home,'' presumably because Respondent will sell its product over the internet. *Id.* at 2.

However, the fact that the FDA approved combination ephedrine/guaifenesin products for OTC use years ago does not establish that there is a continuing need for these products to treat any of the conditions for which these products may be lawfully marketed under the Federal Food, Drug Cosmetic Act, 21 U.S.C. 301–399d. Moreover, as the ALJ observed, Respondent produced no evidence establishing that there is a continuing need for combination ephedrine/guaifenesin products to treat any of the conditions for which they may be lawfully marketed. *See* ALJ at 55–56; *see also Johnson Matthey,* 67 FR at 39042–43 (discussing testimony of a physician and expert in pharmacology that ''derivatives manufactured from narcotic raw materials are necessary to the United States medical community, as there are medical demands that cannot be met by non-opiate narcotics'' and that ''the medical community continues to rely upon opium-derived alkaloids rather than synthetic opiate analgesics'').[2] Nor did Respondent produce any evidence showing that these products have any accepted medical use (*i.e.,* per a doctor's recommendation) beyond those for which they can be lawfully marketed,[3] or produce any evidence that these products are ''necessary to provide for * * * scientific[] or other legitimate purposes.'' 21 U.S.C. 952(a)(1).

The ALJ nonetheless observed that some ''DEA publications * * * may demonstrate some need for ephedrine in the United States for the purpose for which the Respondent proposes to import.'' ALJ at 56 n.21 (citing Final Rule, Registration Requirement for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine, 75 FR 4973 (2010), and Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2011, 75 FR 79407 (2010)). The ALJ thus suggested that I may wish to take official notice of these documents.

However, Respondent did not file exceptions nor otherwise request that I re-open the record to consider these documents. Moreover, even were I do so, neither document establishes that the importation of combination ephedrine/guaifenesin products (as opposed to ephedrine itself) is necessary to provide for medical purposes. For example, while the Assessment of Annual Needs lists several yearly figures for ephedrine sales by registered manufacturers, it does not establish whether any of these sales were for combination ephedrine/guaifenesin products. *See* 75 FR at 79409. As for the Final Rule on the Registration of Importers and Manufacturers of Ephedrine, Pseudoephedrine, and Phenylpropanolamine, while it observes that all three chemicals ''are used to produce drug products lawfully marketed under the'' FDCA, including both prescription and non-prescription drugs, it provides no information as to the need for combination ephedrine/guaifenesin products to provide for medical purposes. 75 FR at 4973–74.

Accordingly, I adopt the ALJ's conclusion that Respondent has failed to establish that its proposed importation is ''necessary to provide for medical, scientific, or other legitimate purposes.'' 21 U.S.C. 952(a)(1). And because establishing its entitlement to a rule authorizing the importation is a prerequisite for Respondent's registration as an importer of ephedrine, its application can be denied on this basis alone.

The Public Interest Factors

The ALJ also found that ''Respondent's registration would be inconsistent with the public interest due to its current inability to comply with state and FDA law, its lack of candor, and its attitude towards diversion.'' ALJ at 80–81. While I agree with the ALJ's ultimate conclusion that Respondent's registration would be inconsistent with the public interest, I disagree with several of her subsidiary conclusions.

The ALJ found that ''the Government has established a clear violation by the Respondent of the FDA's misbranding provisions.'' ALJ at 72. The basis for this finding was the ALJ's conclusion that under the OTC monograph, the label on Respondent's product is required to contain ''under the heading 'indications' '' the following statement: '' 'For temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.' '' ALJ at 72–73 (quoting 21 CFR 341.76(b) & (b)(1)). However, Respondent's proposed label does not. *See* RX 5. While this label does not comply with FDA's requirements, and its product would be deemed misbranded if it was introduced into interstate commerce, 21 U.S.C. 331(b), there is no evidence that Respondent has introduced this product into interstate commerce. Thus, Respondent has not violated the FDCA yet.

In its Exceptions (to the ALJ's first decision), Respondent asserted that these were minor deficiencies which ''are easily rectifiable and will be corrected prior to marketing.'' Resp. Exceptions at 1. While I accept this assertion and conclude that by itself, this would not be ground to deny the application, when considered with

[2] Subsequent to *Johnson Matthey,* other Agency decisions involving narcotic raw materials found, without recounting any medical evidence, that the proposed importations were necessary within the meaning of section 952(a)(1). *See Chattem,* 71 FR at 9835; *Penick,* 68 FR at 6948. However, these cases did not involve show cause proceedings brought by the Agency but rather challenges brought by manufacturers who sought to block the applicant's entrance into the market. *See Chattem,* 71 FR at 9834; *Penick,* 68 FR at 6947. Given that many of these entities were themselves importers of the same narcotic raw materials which the respective applicant sought authority to import, they could hardly claim that the importation of these substances was not necessary for legitimate medical uses and thus did not dispute this proposition. *See Chattem,* 71 FR at 9834; *Penick,* 68 FR at 6949. The same does not hold here.

[3] Noting that in 2004, the FDA banned the marketing of ephedrine as a dietary supplement, the Government equates the statutory term ''medical purposes'' with those indications for which FDA has approved a drug product for marketing. *See* Gov. Exceptions at 5; Gov. Prop. Findings at 6–11 (''DEA law precludes any importation of ephedrine for other than legitimate medical needs and ephedrine is limited to asthma treatment.''). To make clear, this is too narrow a view of what constitutes a valid medical purpose as there may be bona fide medical evidence supporting a product's use, under a physician's supervision, for other than its FDA-approved indications. However, Respondent had the burden of proof on the issue of showing what medical purpose its product would serve and steadfastly maintained that it would serve only the bronchodilator market.

other evidence such as that Respondent's standard operating procedures (SOPs) had numerous inconsistencies with various States' laws, *see* ALJ at 75–77, I conclude that it calls into question its ability to properly comply with applicable Federal and State laws. *See* 21 U.S.C. 823(h)(2).

The ALJ further asserted that ''[d]espite numerous assertions to the contrary, there is substantial evidence that the Respondent would market its product [in a manner] similar to its stated competitor Vasapro,'' an entity, which, the ALJ found markets its product in a manner ''rais[ing] serious misbranding concerns.'' ALJ at 74–75 (citing FoF 91, 92, 102, 111, 124, & 143(d)(vi)).[4] However, in the cited findings, the ALJ noted that Respondent's standard operating procedures required it to market its product only in compliance with the FDCA and the FDA's regulations; that its principal owner testified that it ''would not sell its product for any other purpose than as a bronchodilator''; and that it would not be sold through a Web site (4 Ever Fit USA) its principals own which markets fitness-related products, such as supplements, protein powders and weight-management products. *See* ALJ at 28 (FoF 102); 30 (FoF 111); 33 (FoF 124); and 41 (FoF 143(d)(i)). Given that the ALJ made these findings, several of which were based on the testimony of Respondent's principals and that there is no finding that she found this testimony incredible, it is unclear why the findings provide substantial evidence that Respondent would market its products in violation of the FDCA.

In its brief, the Government argues that Vasapro (as well as Kaizen, a Canadian competitor) marketed ephedrine products for weight loss. *See* Gov. Br. 38. No further explanation was offered as to why Vasapro's conduct is probative of whether Respondent would violate the FDCA, and I conclude that it is completely irrelevant.

The Government also points to the Web sites of two Canadian firms (Kaizen and Gorilla Jack) which it maintains sold ephedrine at retail for non-lawful purposes. *Id.* While the Government maintains that the Kaizen Web site sold ephedrine manufactured by 4 Ever Fit, a firm owned by Respondent's owner, the exhibit it cites as support for this assertion is actually that of an entity known as ''Supplement Source'' and not Kaizen. *See* GX 8. Most significantly, regarding this Web site, an Agency witness testified that: ''and if it works the same as it worked on the other sites that I was on, you would click on [the product category] and then you could pull up the 4 Ever Fit or whatever, they are naming all the brand names and 4 Ever Fit is one of them.'' Tr. 148. However, even ignoring the equivocal nature of this testimony, which strongly suggests that she did not even visit the Web site, none of the eleven ephedrine products shown on the printout include products of 4 Ever Fit. *See* GX 8.

Likewise Government Exhibit 9 (the printout of the GorillaJack.com Web pages) establishes only that this business was selling Kaizen Ephedrine HCL (and not Respondent's or its related firm's product) for its metabolic boosting properties. *See* GX 9, at 8. Thus, the evidence pertaining to the marketing of ephedrine products by these two entities is not relevant in assessing whether Respondent would market its product in violation of the FDCA. I therefore reject as unsupported by substantial evidence the conclusion that Respondent intends to market its product in violation of the FDCA.[5]

This is not to say that the conduct of an applicant's customers (which does not involve diversion of the product into the illicit manufacture of methamphetamine[6]) would never be relevant in assessing its likely compliance with applicable laws related to listed chemicals. *See* 21 U.S.C. 823(h)(2). For example, proof that an entity sold products to a firm when it either knew or had reason to know that the firm was unlawfully marketing the product (*i.e.,* for unapproved purposes) would be relevant in assessing its likely future compliance with applicable laws and the CSA. So too, proof that an entity continued to sell its product to a firm after it knew that the latter had engaged in illegal acts is also relevant in determining the public interest. *See* 21 U.S.C. 823(h)(4) & (5) (authorizing Agency to consider applicant's ''past experience'' in distributing chemicals, as well as ''other factors as are relevant to and consistent with the public health and safety'').

Here, for example, the ALJ found that one of the entities to which a related firm of Respondent[7] distributed ephedrine was Better Bodies Nutrition, a Canadian firm which unlawfully shipped these products to three stores in Arizona in violation of both U.S. and Canadian law because it lacked both a DEA Importer's Registration and a Canadian Dealer's License and Export Permit. *See* ALJ at 22–23; *see also id.* at 68 n.26 (citing 21 U.S.C. 957 and Health Canada, Precursor Control Regulations § 6, 7, 32). The shipments were seized by U.S. Customs and Board Patrol agents at Seattle International Airport, Washington. ALJ at 21–22.

Regarding this incident, Mr. Richard Pierce, Respondent's principal owner (and the CEO of the related companies) testified that he had no knowledge that Better Bodies was selling his firm's ephedrine product to U.S. customers. Tr. 276. However, when asked by the ALJ what his business had done to address this incident, Mr. Pierce testified:

> Well, we have no control over them buying the product from us and shipping it without our knowledge. The regulatory body in Canada has been informed of that, and obviously, Better Bodies is now—my understanding, has dealt with Health Canada in some form or fashion to ensure them that they're not going to do that and understand the repercussions if they do.

Tr. 362.

Notably, Mr. Pierce did not testify that his firms had discontinued supplying Better Bodies with ephedrine products or even that his firms had threatened to cut off Better Bodies if they did so again in the future. Indeed, in its Exceptions, Respondent acknowledges as much, stating that: ''Mr. Pierce iterated that he did still do business with Better Bodies in Canada.'' Resp. Exceptions at 6. While Respondent then asserts that Mr. Pierce simply ''expressed that he had no control over this specific illegal shipment at question,'' *id.,* this misses the point. As the ALJ explained:

> GFR does have control over to whom it sells its product, and GFR's decision to continue to supply a company that has illegally handled its product reflects a general apathy towards diversion * * *. [T]his factor raises a concern that he would similarly turn a blind eye to the misuse of the Respondent's product in the United States.

ALJ at 80.

[4] The correct citation appears to be to FOF 143(d)(vi). *See* ALJ at 41.

[5] In its Exceptions, the Government requests that I ''make a specific finding that [Respondent's] ephedrine market would be consumers who would purchase the ephedrine in violation of the Federal Food, Drug and Cosmetic Act.'' Gov. Exceptions at 1. However, the Government cites no authority for the proposition that a consumer violates the FDCA if he/she purchases an OTC drug product with the intent to use that product for a non-approved (but otherwise legal) use. Accordingly, I decline the Government's request.

[6] Such conduct is always relevant in assessing whether a registrant/applicant has effective controls against diversion. *See* 21 CFR 1309.71(a).

[7] The ALJ found that the product was manufactured by GFR Pharma, and distributed through 4 Ever Fit, Ltd., to Better Bodies Nutrition, the firm which sold the ephedrine to the three Arizona stores. ALJ at 22. There is no dispute that GFR Pharma; 4 Ever Fit, Ltd.; and 4 OTC are related entities, and that Mr. Richard Pierce is the President and CEO of all three entities. RX 4; *see also* ALJ at 18, 24, 25, 27.

Indeed, this Agency has previously revoked a list I distributor's registration based, in part, on similar testimony from its principal. *See D & S Sales,* 71 FR 37607, 37610 (2006) (holding ''fundamentally inconsistent with the obligations of a DEA registrant'' testimony of business owner that ''I could care less about who buys [my products] or who, you know, I have no control over the retail end of those sales. I drop them off to the store and I'm done''). *See also R & M Sales Company, Inc.,* 75 FR 78734, 78745 (2010) (citing testimony of firm's owner that ''I've guess I've taken the attitude that I have no control on what the retail public does with the product'' as evidence of firm's indifference to its obligations to comply with the law).

In its Exceptions, Respondent further argues that the ALJ ''unfairly note[d] Mr. Pierce's attitude towards diversion as one that would be inconsistent with the public interest'' and that ''[t]his factor alone cannot qualify as the preponderance of the evidence that is needed to justify a denial of [its application], when all other factors weigh in favor of granting'' it a registration. Resp. Exceptions at 8.

However, all other factors do not support granting Respondent's application (even ignoring the threshold question of whether it is entitled to a rule authorizing the importation), and in any event, it is settled that findings under a single factor can be sufficient to support the denial of an application. *See Dewey C. Mackay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied* 664 F.3d 808 (10th Cir. 2011). Moreover, there is additional evidence to support the denial of Respondent's application.

Here, the evidence shows that Respondent is a closely-held corporation and that one of its shareholders is Kevin McIsaac, who was a principal and President of McIsaac Distribution Ltd., a firm based in KeLowna Bridge, British Columbia, which sold various products including a single entity ephedrine product under the brand of ''4 Ever Fit.'' Tr. 32, 34, 82; GX 20, at 23. Mr. McIsaac was also President of Respondent and submitted its application for a DEA registration. *Id.* at 34; GX 20, at 24.

On May 27 through 29, 2008, Inspectors from Health Canada conducted an inspection of McIsaac Distribution during which they found various violations. GX 20, at 24–28. Most significantly, Health Canada found that McIsaac had engaged in multiple suspicious transactions involving ephedrine when the firm had ''reasonable grounds to suspect that the transaction is related to the diversion of a precursor to an illicit market or use.'' *Id.* at 26.

These included: (1) a transaction in which McIsaac sent more than 15,000 bottles of ephedrine (6.048 kg) to an individual in Montreal ''representing his business as Liquidation Depot'' while the invoice indicated that the shipment was to be sent to ''Bella Labs'' at an address in Vancouver, B.C., and (2) a shipment of 51,840 bottles of ephedrine (20.74 kg) which was also ''sent on behalf Liquidation Depot'' but ''was sent to the attention of Bella Labs'' at a different Vancouver address. *Id.* at 26. In addition, on two separate dates less than a week apart, McIsaac shipped 2,016 bottles (.8 kg) and 10,080 bottles (4.032 kg) to a post office box in a Mail Boxes Etc. store in Richmond Hill, Ontario; however, the latter shipment was subsequently re-routed to a residential address in the same city. *Id.*

Finally, Health Canada found that between October 8, 2007 and March 25, 2008, McIsaac made ten sales to Liquidation Depot for a total of 137.1 kg of ephedrine; the shipments ranged in size from 15,120 to 51,480 bottles and several involved ''large cash deposits and related bank charges.'' *Id.* at 27. Moreover, some of the shipments occurred either on the same day or within days of previous shipments. For example, on December 21, 2007, McIsaac filled invoices for 34,560 and 34,416 bottles, and on February 28 and 29, as well as March 3, 2008, McIsaac filled invoices for 40,992; 51,480; and again 51,480 bottles respectively. *Id.* at 27. Health Canada ''noted that the quantities of ephedrine * * * sold to Liquidation Depot during this period far exceeded the quantities purchased by all other clients.'' *Id.*

Health Canada further advised McIsaac ''that as a licensed dealer,'' his firm was not permitted to ''sell a Class A precursor to a person for any licensed activity (export, produce, package, sell and provide), unless that person holds the appropriate license or is exempted under section 5'' of its Precursor Control Regulations. Health Canada also expressed its ''concerns about [McIsaac's] capacity to comply with the regulatory requirement to detect and record suspicious transactions.'' *Id.*[8] While Health Canada directed Kevin McIsaac to submit a written corrective action plan, McIsaac notified Health Canada that he was cancelling his Canadian Chemical Precursor license and that he had sold his business to GFR Pharma, Ltd. *Id.* at 29–30. However, according to Richard Pierce, McIsaac had sold only the assets of 4 Ever Fit to GFR Pharma. Tr. 260.

At the hearing, Mr. Pierce asserted that neither Kevin McIsaac nor his brother are involved in the day-to-day operation of GFR Pharma and do not own any part of this business. Tr. 273. However, Mr. Pierce subsequently acknowledged that Kevin McIsaac owns ten percent of Respondent but then denied that he is involved in its day-to-day operations.[9] *Id.* at 284. Mr. Pierce further testified that he owns sixty percent of Respondent through his ownership of 4 Pharma, LLC. *Id.* at 364. While other testimony establishes that fifteen percent of Respondent is owned by one Mike Schiefelbein, the President of 4 EF, Inc. (another firm owned by Richard Pierce through his ownership of 4 Pharma, LLC, and which does business as 4 Ever Fit USA, *id.* at 280–81, 373), this only accounts for eighty-five percent of Respondent's ownership.

While noting that she was ''troubled by Mr. McIsaac's violations of Canada's regulations'' which she found ''to be more significant than GFR's,'' the ALJ was ''persuaded by the fact that Mr. Schiefelbein will oversee the day-to-day operations of the company and that Mr. McIsaac will have no participation in that operation.'' ALJ at 70. Unlike the ALJ, I find that Mr. McIsaac's ownership interest in Respondent (without regard to whether he will be involved in its day-to-day operations) provides ample reason to warrant the denial of its application.

As found above, the findings set forth in the Health Canada letter support the conclusion that these products were likely diverted into the illicit manufacture of methamphetamine. As the Canadian authorities found with respect to the transactions, there were ''reasonable grounds to suspect that the transaction[s] [were] related to the diversion of a precursor to an illicit market or use.'' GX 20, at 25 (citing Precursor Control Regulation 86). In short, given the quantities involved and the circumstances (such as cash payments, different billing and shipping addresses, frequency of the transactions, shipping to a P.O. Box and/or re-routing the shipment to a residence, and shipping large quantities to non-licensed entities), there is substantial evidence that McIsaac sold ephedrine to customers who were likely diverting it

[8] Apparently, under Canadian regulations, a licensed dealer is only ''required to record'' and not report ''any suspicious transaction.'' GX 20, at 25 (citing Health Canada, Precursor Control Regulations 86). Under U.S. law, a regulated person must report suspicious transactions. *See* 21 U.S.C. 830(b)(1)(A).

[9] An Agency DI contended that Mr. McIsaac actually owns 70% of Respondent. Tr. 34–35.

into the illicit manufacture of methamphetamine.[10]

In a long line of cases, ''DEA has consistently held that the registration of a corporate registrant may be revoked upon a finding that a natural person who is an owner, officer, or key employee, or who has some responsibility for the operation of the registrant's controlled substance business, has been convicted of a felony offense relating to controlled substances.'' *Absecon Pharmacy;* 55 FR 9029, 9030 (1990) (citing cases). Likewise, the Agency has applied this rule in other cases where there is proof that a corporate applicant's owner, officer, or key employee has engaged in diversion or otherwise violated applicable laws. *See Orlando Wholesale, L.L.C.,* 71 FR 71555, 71557 (2006) (denying application noting evidence that ''one of Respondent's managing members had previously operated a business which distributed List I chemicals without a valid registration and [that Respondent] fail[ed] to provide any documentation that this individual no longer has a management or *ownership interest* in it'') (emphasis added); *City Drug Co.,* 64 FR 59212, 59214 (1999) (holding, where former owner had diverted controlled substances, that the Agency ''may look to who exerts influence over the registrant; sometimes the bonds linking the former owner to the new owner are too close to ensure that the former owner will have no influence over the operation of the'' registrant).

While Respondent maintains that Mr. McIsaac will have no involvement in its day-to-day operations, given his ownership interest in Respondent, which is a closely held corporation, it strains credulity to suggest that he will not have some influence over its business and policies. In any event, in making the public interest determination, DEA is authorized to consider an applicant's ''past experience * * * in the distribution of chemicals'' as well as ''other factors [that] are relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h)(4) & (5). When an applicant's ownership group includes a person who clearly diverted either listed chemicals or controlled substances, that conduct is properly considered against the applicant as ground to deny the application.[11]

Moreover, even crediting Respondent's evidence as to the respective ownership interests of Mssrs. Pierce, Schiefelbein, and McIsaac, it has offered no evidence as to who owns the remaining fifteen percent of it. As noted above, DEA has long held that misconduct committed by an entity's officers or key employees is ground to deny an application. Thus, in addition to Mr. McIsaac's involvement, because Respondent has not disclosed who the remaining owners are, there are further grounds to deny the application.

Finally, Respondent contends that it has ''demonstrated a strong understanding for regulations that govern the * * * sale of ephedrine within the United States'' and that Mssrs. Pierce and Schiefelbein have expressed their intent and commitment to remaining compliant with both federal and state laws.'' Resp. Exceptions, at 4. Yet at the hearing, the Government established multiple instances in which Respondent's standard operating procedures were inconsistent with various state laws applicable to the sale of ephedrine products. *See* ALJ at 36–39. Moreover, while some States have made ephedrine a scheduled drug, Mr. Pierce stated that he was ''unfamiliar'' with drug schedules. Tr. 345. Also, while Respondent seeks registration to operate in Arizona, at the time of the hearing, it did not have an Arizona Board of Pharmacy ephedrine wholesaler's license to import ephedrine into the State and Mr. Pierce was unaware that Respondent needed this license until it was pointed out to him by Government counsel on cross-examination. Tr. 371, 443.

In its Exceptions, Respondent argues that it ''recognize[s] the need to remain abreast of regulations and [has] expressed its intent to continuously work with regulatory counsel * * * to remain knowledgeable on key changes in state laws.'' Resp. Exceptions at 5. However, it is not too much to expect that an applicant seeking to show its intent to comply with applicable state laws, would produce SOPs which were not riddled with misstatements of those laws and which correctly reflected those States where its proposed method of operation would be unlawful. Accordingly, I find Respondent's exception unpersuasive.

In conclusion, I hold that the Government's contention that Respondent would market its product in violation of the FDCA to be unsupported by substantial evidence. I also conclude that there is no basis in law for the Government's contention that a consumer violates the FDCA if he/she purchases an ephedrine product with the intent to use it for a purpose which has not been approved by the FDA.[12]

Nonetheless, I find that substantial evidence supports the denial of Respondent's application for registration. This evidence includes: (1) Mr. Pierce's continuing to sell ephedrine products to Better Bodies, notwithstanding that it had unlawfully exported ephedrine to three stores in Arizona, and his insistence at the hearing that he has no control over what his customers do with his products; (2) that on multiple occasions, Mr. McIsaac, who has a substantial ownership interest in Respondent, sold ephedrine under circumstances which provided reason to believe that the ephedrine would be diverted into the illicit manufacture of methamphetamine; (3) that even crediting Mr. Pierce's testimony regarding the respective ownership interests in Respondent, he did not account for the remaining fifteen percent; and (4) that even as of the date of the hearing, Respondent's SOPs still did not accurately reflect various State laws prohibiting its proposed method of distribution. Accordingly, I also adopt the ALJ's ultimate conclusion that Respondent's registration would be

[10] Even though this conduct occurred in Canada and thus cannot be considered under factor two, it is actionable under either factor four, which authorizes the consideration of ''any past experience of the applicant in the * * * distribution of chemicals,'' or factor five, which authorizes the consideration of ''such other factors as are relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h). It should be further noted that had McIsaac committed this conduct in the United States, he would have committed a felony offense. *See* 21 U.S.C. 841(c) (providing that ''[a]ny person who knowingly or intentionally * * * possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by'' the CSA ''shall be fined in accordance with Title 18 or imprisoned not more than 20 years'').

[11] I do not find it persuasive that Mr. McIsaac owns only ten percent of Respondent. In other contexts, an ownership interest of five percent by a person who has engaged in misconduct has been deemed sufficient to bar the entity from participating in a federal program. *See* 42 U.S.C. 1320A–7(b)(8) (authorizing exclusion from participation in federal health care programs of an entity controlled by a sanctioned individual ''who has a direct or indirect ownership or control interest of 5 percent or more in the entity''); *see also id.* 1320A–3(a)(3) (defining ''the term 'person with an ownership or control interest' '' to include ''a person who * * * has directly or indirectly * * * an ownership interest of 5 per centum or more in the entity''). This is not to suggest that if Mr. McIsaac owned less than five percent of Respondent, his ownership interest would not bar granting Respondent's application.

[12] However, under the CSA, ''[a]ny person who knowingly or intentionally * * * possesses a listed chemical [such as ephedrine] with intent to manufacture a controlled substance except as authorized by'' the CSA, or who ''possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by'' the CSA, commits a felony offense. 21 U.S.C. 841(c)(1) & (2).

''inconsistent with the public interest.'' 21 U.S.C. 823(h).

Because Respondent has not established that it is entitled to a rule authorizing the importation of its combination ephedrine products and the Government has established that Respondent's registration would be ''inconsistent with the public interest,'' *id.,* I will adopt the ALJ's recommended order. ALJ at 81. Respondent's application will therefore be denied.[13]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) and 958(c), as well as 28 CFR 0.100(b), I order that the application of 4 OTC Inc., for a DEA Certificate of Registration as an Importer of List I chemicals, be, and it hereby is, denied. This Order is effective July 12, 2012.

Dated: June 4, 2012.

Michele M. Leonhart,

Administrator.

Brian Bayly, Esq., for the Government
Ashish Talati, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

I. Procedural Background

Administrative Law Judge Gail A. Randall. On April 6, 2010, the Deputy Assistant Administrator, Drug Enforcement Administration (''DEA'' or ''Government''), issued an Order to Show Cause (''Order'') proposing to deny (1) the application of 4 OTC, Inc., (''Respondent'' or ''4 OTC'') to import the list I chemical ephedrine pursuant to 21 U.S.C. § 958(c)(2) and 958(d)(2), because 4 OTC's import registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(h); (2) 4 OTC's two applications to distribute the list I chemical ephedrine pursuant to 21 U.S.C. 823(h), because 4 OTC's distribution registrations would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h); and (3) 4 OTC's application to export the list I chemical ephedrine pursuant to 21 U.S.C. § 958(c)(2) and 958(d)(2), because 4 OTC's export registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(h). [Administrative Law Judge Exhibit (''ALJ Exh.'') 1].

The Order asserted that 4 OTC is a company that currently sells over-the-counter nutritional supplements to customers who solicit such products over 4 OTC's website, for health and fitness. 4 OTC plans to import finished form, combination ephedrine from a Canadian company and sell the product via the internet to ultimate consumers in the U.S. and other countries.

Further the Order asserted that 4 OTC's application to import should be denied on the basis that it did not identify its customer in the United States, either retail or mail order, and 4 OTC was not familiar with DEA laws pertaining to domestic distribution sales limits as well as other application laws. [Order at 2 (citing 21 U.S.C. § 823(h)(1), (h)(2), and (h)(5))].

In addition, the Order stated that the Respondent's applications should be denied based on its common ownership with McIsaac Distribution, which merged with GFR in 2008. The Order provided that GFR would be the Respondent's supplier and that Health Canada cited both McIsaac and GFR for failure to report to Health Canada suspicious sales of ephedrine products, for shipping ephedrine products to unverified addresses and for a shortage of .008 kilograms of ephedrine based upon an accountability audit. [*Id.*].

The Order further alleges that GFR and McIsaac's ephedrine sales records reveal other suspicious sales of ephedrine that were not cited by Health Canada but that would be violations of 21 U.S.C. 830(b)(1)(A) because such sales involved an extraordinary quantity or were made to retail outlets that do not normally sell ephedrine products, such as gymnasiums. [*Id.* (citing § 823(h)(1), h(4), and (h)(5))].

The Order alleged that although the Respondent's personnel stated that 4OTC's product, labeled ''4 Ever Fit,'' would be marked only as an OTC medication to treat asthma, 4 OTC's present customers and product lines are not consistent with this professed intent, and that the product would be imported for other than a legitimate medical purpose. [*Id.* (citing § 823(h)(1), (h)(2), (h)(5) and 952(a)(1))].

Last, the Order alleged that the Respondent's applications should be denied on the basis that 4 OTC's ephedrine brand product, ''4 Ever Fit,'' was seized at the Canadian borders when Better Bodies Nutrition attempted to ship it illegally into the U.S. to stores who plan to market the product as a weight loss product, and hence, the company has failed to maintain effective controls against diversion. [*Id.* at 3 (citing 823(h)(1))].

On May 7, 2010, the Respondent, through counsel, timely filed a letter requesting a hearing in the above-captioned matter. [ALJ Exhibit Exh. 3].

On May 24, 2010, the Government filed a Motion For Summary Judgment And To Stay The Dates For The Parties To Submit Prehearing Statements (''Motion for Summary Judgment''). [ALJ Exh. 4]. Therein, the Government moved for summary judgment on the basis that the Respondent lacked a bona fide registered address. The Government stated that it unsuccessfully attempted to serve the Respondent with the Order to Show Cause at the address listed in its application as its registered address, 8160 Blakeland Dr., Littleton, Colorado 80125. In addition, the Government stated that the DEA later visited that location and discovered that the Respondent was not located at that address. [*Id.* at 1–2].

In a letter dated June 10, 2010, the Respondent requested to amend its application by changing its proposed registered address from 8160 Blakeland Drive, Littleton, Colorado 80125, to Freeport Logistics, 431 N. 47th Avenue, Phoenix, Arizona 85043. [ALJ Exh. 15].

On June 14, 2010, the Respondent filed its response to the Government's Motion for Summary Judgment. Therein, the Respondent stated that it had moved to a new location in Phoenix, Arizona, and that the Respondent's counsel had spoken with the Government's counsel, and the Government's counsel had no objection to it amending its application to include a new registered address. The Respondent stated that it had already begun the process to amend its applications. [ALJ Exh. 5 at 1–3].

In a letter dated November 10, 2010, the Respondent sought to withdraw its applications to export ephedrine, to distribute ephedrine, and to distribute ephedrine at retail. [ALJ Exh. 17 at 5].

Because those requests were issued after the Order to Show Cause, the Respondent was required to request permission to amend its application and withdraw three of its application. [ALJ Exh. 17 at 3 (citing 21 CFR 1301.16(a))].

The Deputy Assistant Administrator granted both requests on April 13, 2011. [*Id.* at 3].

The hearing was held on January 19, 2011, at DEA Headquarters in Arlington, VA. It continued on March 9, 2011, in Phoenix, Arizona. [ALJ Exh. 14, 16].

[13] Because there are ample grounds to deny the application, I conclude that it is not necessary to decide the question of whether the Agency can require an applicant for an Importer's registration to provide a customer list as a condition of granting its application. *See* ALJ at 78–79. I therefore do not adopt the ALJ's discussion, which suggests that because neither the Combat Methamphetamine Epidemic Act nor Agency regulations require that an importer produce a customer list at the time it seeks registration, the Agency cannot require such. *See id.; but see* 21 U.S.C. 823(h)(1) (directing Agency to consider whether an applicant will maintain effective controls against diversion); 21 CFR 1309.35 (authorizing Agency to ''require an applicant to submit such documents or written statements of fact relevant to the application as [it] deems necessary to determine whether the application should be granted'').

II. Issue

The remaining issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration should deny 4OTC's application for a DEA Certificate of Registration to import the list I chemical ephedrine into the United States because to grant the Respondent's application would be inconsistent with the public interest pursuant to 21 U.S.C. § 823(h), 958(c)(2), and 958(d)(2). [Tr. 5–7].

III. Findings of Fact

A. Stipulated Facts

1. Ephedrine is a list I chemical. [21 CFR 1310.02(a)(3)].

2. Ephedrine is also classified as a Scheduled Listed Chemical Product (''SLCP'') under the Combat Methamphetamine Epidemic Act of 2005 (''CMEA''). 21 U.S.C. 802(45)(A); 21 CFR 1300.02(34)(i).[1] [ALJ Exh. 15].

B. Background

1. Ephedrine

3. The CMEA aimed to enhance controls of chemicals and equipment that are used in the clandestine manufacture of methamphetamine and other illegal substances. [Tr. 27, 242].

4. Ma Huang and Ephedra are ephedrine products. [Tr. 94, 141].

a. Sale and Use of Ephedrine as a Dietary Supplement

5. In 2003, the Administrator of the Department of Health and Human Services (''DHHS'') pulled ephedrine off of the market as a dietary supplement. [Tr. 141]. The ban went into effect in 2004. [Tr. 148].

6. Ma Huang may be sold as a dietary supplement in Canada, however. [*See* Tr. 161].

7. Using ephedrine as a dietary supplement poses serious health risks. According to an article introduced by the Government, ''the FDA has on record over 80 deaths and 1400 adverse-effect complaints, including strokes, coronaries, and seizures.'' [Govt. Exh. 17 at 2]. Further, the article notes that ''nearly all the deaths and complications from the use of ephedra are the result of gross abuse of the product . . ..'' [*Id.*].

8. The DEA has not promulgated regulations restricting or prohibiting the importation of ephedrine into the United States for the purpose of weight loss. [Tr. 168]. In addition, the DEA does not currently prohibit the sale of ephedrine products for weight loss. [Tr. 244]. However, since 2004, the Food and Drug Administration (''FDA'') has banned the sale of an ephedrine product as a dietary supplement. [Tr. 148; *see also* 69 FR 6788 (2004)].

b. Product Trends

9. John Kronebusch is a program analyst at DEA. [Tr. 53]. He has worked in that capacity since 1990. [Tr. 54].[2]

10. Mr. Kronebusch credibly testified that there are substantially more mail order reports for pseudoephedrine products than ephedrine products. [Tr. 60].

11. Mr. Kronebusch testified that most of the pseudoephedrine and ephedrine reports are submitted by well-known national companies such as CVS, Drugstore Pharmacy, or Eckerd. [Tr. 61].

12. Mr. Kronebusch testified that there has been a significant decline in ephedrine transactions since 2008. [Tr. 61–2]. Two companies, who had prior to 2009 reported significant numbers of mail order sales of ephedrine, closed their mail order business in 2009. [*Id.*].

2. DEA's Retailer Requirements

a. Retail Sales Limit

13. The DEA does not require mail order distributors[3] of ephedrine products to register with the DEA. [Tr. 57]. However, the DEA imposes daily and monthly sales limits on the amounts retailers may sell to one person and requires that they report their sales on the 15th of every month to the DEA. [Tr. 35–36, 54–55]. The reports required by DEA must identify the purchaser of the List I chemical product. [Tr. 56–57]. A government ID or driver's license would satisfy this requirement. [Tr. 57].

14. The retail sales limit for ephedrine used to be 24 grams per month but is now 3.6 grams per day per person, and 7.5 grams per month. [Tr. 35–36].

15. The retailer is also required to keep a record of all ephedrine sales. [Tr. 36, 51–2, 432].

b. Self-Certification

16. The owner of a retail distributor of list I chemicals must become self-certified with the DEA. [Tr. 229–230]. To do so, the owner must go online and follow several steps, including: teaching his employees who have the ability to sell the product over the counter about the thresholds for daily and monthly purchases and developing a logbook for sales. [Tr. 230]. The retailer must then display its retail self-certification in its store prior to selling the product. [Tr. 230]

3. DEA's Importer Requirements

17. The DEA requires an importer to obtain an importer registration to import list I chemicals into the United States, and to fill out a Form 486, 15 days prior to any importation, notifying the DEA of an upcoming import. [Tr. 231–233].

a. Requirement of Providing a Customer List

18. According to Marian Klett, a program analyst in the Office of Diversion Control at DEA,[4] the DEA requires applicants for importer registrations, even those who have yet to go into business, to include in their application a list of proposed customers. This requirement began as DEA policy pursuant to a mandate by the Department of Justice that the DEA establish protocols to better regulate precursors to methamphetamine production. [Tr. 170–71; 445–9].

19. Ms. Klett testified that as of 2000, the DEA will not grant a DEA registration if an applicant does not have a customer list, because the agency cannot determine whether the product will be diverted. [Tr. 446]. This is not, however, a requirement for domestic mail order sales, i.e. retail distributors. [Tr. 446].

20. After the applicant provides a list of customers, the DEA will then verify those customers. [Tr. 447–8]. Ms. Klett testified that when Congress passed the CMEA, it put specific language in the act that mandated the DEA to ask for downstream customers from the proposed importer. The DEA does so for importers on its Form 486A. [Tr. 448–9].

21. As for start-up companies, Ms. Klett testified that how the company ascertains its downstream customers is up to them. [Tr. 450].

22. Ms. Klett testified that the DEA has never before entertained an importer application for a company that wished to sell strictly retail. [Tr. 453]. In addition, she testified that the form 486 requires a customer list, which is a form that the registrant fills out prior to the

[1] The remaining stipulated facts repeat the procedural history of this case. [ALJ Exh. 15].

[2] Mr. Kronebusch manages a database that contains firms that handle List I or List II chemicals. [Tr. 54]. Since 2007, he has also been assigned oversight of mail order firms. [Tr. 54].

[3] Retail distributors sell to non-regulated persons, i.e. persons that will use rather than redistribute the ephedrine product. [Tr. 55, 57]

[4] Ms. Klett has been in that position since 1997 and has been with DEA since 1995. Ms. Klett conducts a preliminary review of incoming List I chemical pre-registration packages. The preregistration package contains all documents that are forwarded by the applicable field office to the DEA when a company applies for a DEA registration. Ms. Klett is familiar with the Combat Methamphetamine Act. [Tr. 119–120]. Prior to working as a Program Analyst, Ms. Klett was an Intel Research Specialist from 1988–1997. In addition, from January 2000 to February 2003, Ms. Klett was an Intel Analyst in the Office of Diversion Control for an LSD investigation. [Tr. 122].

actual importation, and post registration. [Tr. 452–53].

b. Canadian Regulation of Ephedrine

23. Diversion Investigator David Hargroder[5] (''DI Hargroder'') testified about information he obtained from Health Canada, the Canadian agency that regulates listed chemicals. [Tr. 84]. DI Hargroder testified that Canada's regulation of List I Chemicals is similar to the DEA's. [Tr. 80]. He testified that Health Canada requires entities to obtain Class A Licenses. [Tr. 80].

C. The Respondent

24. The Respondent, 4 OTC, Inc. (''4 OTC'') is a company seeking to import finished form ephedrine products into the United States and to sell it to retail customers via the internet. [Tr. 33, 393].

25. The Respondent intends to store the listed chemical products in a warehouse in Phoenix, Arizona. [Tr. 337]. 4 OTC is ready for operation but not yet up and running. [Tr. 255].

26. The Respondent first applied for a DEA registration on August 14, 2007. [Respt. Exh. 1].

27. Richard Pierce, who testified on behalf of the Respondent, stated that 4 OTC would only sell its ephedrine product as a bronchodilator. [Tr. 277].

1. Initial Investigation

28. In January of 2008, Richard Quintero, a Diversion Investigator for the DEA in the Denver Colorado division,[6] traveled to the Respondent's proposed location at 8160 Blakeland Drive, Unit H, Littleton, Colorado 80125. [Tr. 27–28].

29. During that visit, DI Quintero met with the Respondent's Vice President, Mike Schiefelbein. DI Quintero asked Mr. Schiefelbein basic information about 4 OTC, including the company from whom the Respondent intended to import ephedrine, the person who would maintain record-keeping and security, and the Respondent's intended customers. [Tr. 28–29].

30. In July of 2008, DI Quintero returned to the Respondent's proposed location, at 8160 Blakeland Drive, to conduct a second investigation of 4 OTC. [Tr. 29]. On that visit, DI Quintero was accompanied by Dan McCormick, another Diversion Investigator from the Denver, Colorado field division. [Tr. 30].

31. However, on that visit the Respondent was no longer located in Unit H; it was then located in Unit C of the same address. [Tr. 29]. The Respondent was renting a small part of this warehouse from Allison Medical Supply on a month to month basis per an oral agreement. [Govt. Exh. 12 at 1–2]. The Respondent had advised the DEA of the new address via telephone yet had not submitted a written request for an address modification. [Govt. Exh. 12 at 1].

32. On May 12, 2010, DIs Quintero and McCormick returned to Unit C. [Tr. 39]. The receptionist told the DIs that 4 OTC was no longer at that location. The receptionist stated that the Respondent had moved to Arizona and not left a forwarding address. [Tr. 39]. The local post office also had no record of a forwarding address for 4 OTC. [Tr. 40; Govt. Exh. 12 at 2]. The Respondent had not advised the DEA of the new address. [Govt. Exh. 12].

2. Current Location

33. Respondent is currently located at Freeport Distribution's Warehouse, 431 N. 47th Avenue, Phoenix, AZ 85043. [Resp. Exh. 9 at 1]. The warehouse is also occupied by other tenants. [Tr. 396–97].

34. Mr. Pierce testified that the Respondent's facility was inspected by the DEA and that, to his knowledge, the agency did not have any issues with the security. [Tr. 285]. In addition, the Respondent hired a consultant, John Mudri,[7] who inspected the facility and testified he observed where the ephedrine product would be located, whether there were alarm transceivers, the doors, gating, and who had access. [Tr. 410–11]. He testified that the Respondent's security features are ones that an entity would consider if securing Schedules III through V controlled substances and thus are greater than that required for scheduled listed chemicals. [Tr. 410–412].

35. Respondent introduced a document from Freeport Distribution which describes the security and building features of the warehouse. [Resp. Exh. 9]. Mr. Mudri testified that this document accurately reflects the Respondent's warehouse security. [Tr. 410–412]. Among those listed, the Respondent stated that all warehouse employees undergo background checks, including screens for substance abuse, that the warehouse is guarded by two guards during non-operational hours but guards do not have keys or access to the facility, that there are cameras in place, and that the facility is completely fenced with an 8 foot fence topped with razor wire. [Respt. Exh. 9 at 1]. The document further states that ''all Freeport contractors for hire must show proof of background checks for anyone entering'' the facility. [Resp. Exh. 9 at 1].

3. Respondent's Source

a. McIsaac Distribution

36. The Respondent originally listed McIsaac Distribution as the source from which it would import ephedrine. [Govt. Exh. 11]. McIsaac Distribution is a Canadian distributor of sports nutrition products such as protein powders, and other natural health products. [Govt. Exh. 20 at 17]. It used to sell a product called 4 Ever Fit, a single-entity ephedrine product. It sold 4 Ever Fit as a muscle building and weight loss product in Canada to mostly retail locations such as gyms and health and fitness stores. [Tr. 122–129; Govt. Exh. 20 at 6–8].

37. McIsaac Distribution is located in KeLowna Bridge, Columbia in Canada. [Tr. 32, 82].

38. Kevin McIsaac is the president of McIsaac Distributions. [Tr. 34, 82; Government Exhibit (''Govt. Exh.'') 12 at 1]. He was also the original signee on the Respondent's importation application. [Tr. 34].

39. McIsaac Distribution possessed a Class A precursor license in Canada, that it later withdrew. [*See* Govt. Exh. 10].[8] McIsaac Distribution relinquished its Class A precursor license because it was ''no longer able to sell ephedrine.'' [Tr. 260].

[5] David Hargroder is a Diversion Investigator at DEA Headquarters. [Tr. 77]. DI Hargroder conducts chemical investigations involving ephedrine, pseudoephedrine, and methamphetamine. [Tr. 77]. DI Hargroder started his law enforcement career at DEA in 1980, prior to which he served as an investigator in various territories and worked for the New Orleans Police Department. [Tr. 77]. He currently serves as a staff coordinator for the pharmaceutical section of the Office of Divergence and Synthetic Chemicals (''ODS'') at DEA. He was transferred to that section only three days prior to the hearing, before which he served for the chemical section of ODS. [Tr. 78–79]. There, he was responsible for reviewing pre-registration investigations involving appeal. [Tr. 79].

[6] [Tr. 25; Govt. Exh. 12 at 1]. DI Quintero has worked in that capacity for 12 years. [Tr. 26]. DI Quintero was assigned to investigate the List I chemical applications of the Respondent. [Tr. 27].

[7] [Tr. 380, 398]. Mr. Mudri began working for DEA as a Diversion Investigator in 1972 in the Cleveland, Ohio branch. He then served as a Senior Investigator for that branch from 1974–1979. From 1979 to 1986, he served as an Investigative Supervisor in the Detroit, Michigan branch and later served in the same capacity in Tampa, Florida. He became a Staff Coordinator for the Diversion Policy Section of DEA in 1993, and held that same position in the Diversion Liaison Section from 1995–1996. From 1996–1998, he was the Chief of the DEA's Domestic Chemical Operations section. He then became a Senior Investigator again in 1998 for the Tampa, Florida branch, after which he left DEA in 2001. [Respt. Exh. 11 at 2]. In addition to consulting, as well as other professional activities, he currently teaches a course called Controlled Substances Laws in the University of Florida graduate pharmacy program. [Tr. 401–2].

[8] On its precursor license application, the company stated that it intended to purchase ephedrine, ''MaHuang,'' from GFR and Biopark Ltd. [Govt. Exh. 20 at 19].

40. In 2008, McIsaac Distribution sold certain assets, including the 4 Ever Fit product, to GFR Pharma. [Tr. 33, 106, 258, 262, 294; Respt. Exh. 8; Govt. Exh. 20 at 30, 46–47].

41. GFR Pharma Ltd. (''GFR'') is a company located in Maple Ridge, British Columbia, Canada. [Tr. 33; 252]. The company used to be named GFR Nutritionals Ltd. [Govt. Exh. 20 at 5]. Prior to its purchase of assets from McIsaac Distribution, GFR Pharma manufactured and sold 4 Ever Fit to McIsaac Distribution. [Tr. 294–5].

42. Prior to the sale of certain assets to GFR Pharma, McIsaac Distribution was inspected by Health Canada. [Govt. Exh. 20 at 24]. Health Canada noted several concerns. First, it noted that McIsaac Distribution had failed to obtain the Minister's approval prior to making changes of its internal protocols as cited in its initial application. Specifically, in contrast to what was stated on its application, McIsaac failed to lock the drawer that contained the key to the Class A precursor cage. In addition, McIsaac failed to keep an ephedrine movement log. Next, Health Canada noted McIsaac's recordkeeping violations, including failing to record cage ephedrine movements and failing to record the full name of person(s) accessing the cage. Last, Health Canada noted several ''suspicious transactions'' that the company failed to record. A suspicious transaction is one where ''there are reasonable grounds to suspect that the transaction is related to the diversion of a precursor to an illicit market for use.'' Some of the factors that Health Canada lists as to being indicative of diversion are: (1) delivery by dubious route; (2) Using a private house or post office box number as the address from which the order is made; and (3) irregular order and quantities. The agency found two transactions that were delivered by dubious route, where a combined total of 66,960 bottles of hydrochloride ephedrine (26.778 Kg) were sent from McIsaac Distribution via Liquidation Depot to Bella Labs. Each shipment listed a separate address for Bella Labs, and the first shipment's address for Bella Labs was deemed not a legal address. Next, the agency found two instances where a combined total of 12,096 bottles of ephedrine chloride (4.832 Kg) were shipped to a post-office box in a Mail Boxes, Etc., of which the second shipment was rerouted to a residential address. The agency then found that McIsaac Distribution's largest sales between April 27, 2007, and May 27, 2008, were to Liquidation Depot (a total of 341,952 bottles of hydrochloride ephedrine were sold) and ''these transactions were * * * suspicious because they were triggered by large cash deposits and related bank charges.'' Health Canada noted that in light of the foregoing it had ''strong concerns about [McIsaac Distribution's] capacity to comply with the regulatory requirement to detect and record suspicious transactions.'' [Govt. Exh. 20 at 24–27].[9]

43. In response to those suspicious transactions, on November 19, 2008, Health Canada ordered McIsaac Distribution to submit a ''written corrective action plan'' to it by December 19, 2008. [Govt. Exh. 20 at 28; Tr. 159]. Prior to that order, however, on November 17, 2008, McIsaac Distribution notified Health Canada, by email, of its sale to GFR. On November 19, 2008, Health Canada received an email from McIsaac Distribution reflecting its desire to close its Class A Precursor License. [Govt. Exh. 10]. On December 3, 2008, McIsaac Distribution faxed Health Canada a document regarding the closure of its Class A Precursor License. [Govt. Exh. 20 at 30].

44. A review of the 4 Ever Fits sales list, while that product was sold by McIsaac Distributions, revealed an internet sale of 10 bottles of ephedrine hydrocholoride 8 mg to Marcy LeBlanc, whose address could not be confirmed, and a sale of 96 bottles of ephedrine hydrochloride 8 mgs to Body FX, whose address also could not be confirmed. [Tr. 139–140; Govt. Exh. 20 at 48].

45. In addition, many of 4 Ever Fit's customers as of 2007 were health and fitness stores. [*See* Gov't. Exh. 20 at 6–15]. A few of those customers contained on that list had addresses in the United States. [*See id.* at 6, 15 (listing 12 locations for Bally Total Fitness in Chicago, Illinois and one location for Vitamin World in New York)]. However, a second report documenting actual ephedrine sales for January of 2007, fails to record any sales of the 4 Ever Fit product to U.S. companies. [*Id.* at 41–44].

b. GFR Pharma, Ltd.

46. The Respondent maintains that it will purchase its ephedrine product from GFR Pharma (''GFR'') and not McIsaac Distribution. [Tr. Govt. Exh. 11 at 2].

47. Richard Pierce is the President and CEO of GFR. [Tr. 252]. As President and CEO of GFR, Richard Pierce runs the day-to-day operations of the corporation, including overseeing quality control, purchasing, sales, and marketing. [Tr. 252]. He has dealt with the sale of ephedrine since 2004. [Tr. 252].

48. According to Mr. Pierce, Kevin McIsaac has no role at GFR Pharma. [Tr. 259].

49. GFR currently has its own Canadian precursor license. [Resp. Exh. 8; Tr. 102]. ''As a holder of this license, GFR is authorized to produce, package, sell, import, and export precursor substances such as ephedrine (both ephedrine salt and Ma Huang).'' [Govt. Exh. 11 at 2].

50. GFR manufactures ephedrine by purchasing the raw material from a registered supplier with a precursor license. The quantities of that purchase are verified by the Canadian government. The raw material is then immediately put in a holding cage that is locked and monitored by camera. The ephedrine is then quality-control inspected and released for manufacturing. The ephedrine is then blended with the proper ingredients. The raw material is placed back into the holding cage. The product is once again removed and placed in a tablet press, placed back into the cage, and then sent to be packaged, after which it is once again placed in the cage. [Tr. 256–57].

51. GFR manufactures approximately 200 kilograms of ephedrine per year. [Tr. 253].

52. GFR converts that ephedrine into 25 million tablets. [Tr. 253–254, 257].

53. The brand of ephedrine product that GFR markets in Canada is 4 Ever Fit. [Tr. 254]. Richard Pierce testified that the product is used as a decongestant in Canada. [Tr. 254]. However, 4 Ever Fit's customer list suggests that product is sold as a dietary supplement in Canada. [*See* Govt. 20 at 42–44 (listing the purchase of 4 Ever Fit by numerous health food stores and gyms)].[10]

54. Mr. Pierce testified that he has never sold this product to a U.S. based company because that would be illegal. [Tr. 254]. Mr. Pierce testified that in Canada ''we can sell it to health food stores * * * to sports nutrition stores, a wide variety [of stores].'' [Tr. 254].

55. The DEA obtained information from Health Canada regarding GFR Pharma. including any and all audits, photos, copies of registration forms, product distribution lists, copies of all Canadian licenses, formal letters between Health Canada and the

[9] Ms. Klett found it most noteworthy that Health Canada believed there were ''suspicious transactions'' between McIsaac and its purchasers that McIsaac failed to report to Health Canada. Ms. Klett testified that the DEA finds any kind of cash transaction, above the retail level, suspicious. [Tr. 136].

[10] In addition, I do not find this statement of Mr. Pierce's credible, as it is unreasonable that persons would purchase a product labeled ''4 EverFit'' as a nasal decongestant. In addition, he is not qualified to testify as to how his product is actually used by GFR's customers. T

company, export documents, documents regarding the sale of McIsaac Distribution to GFR Pharma, documents regarding the transfer of products from McIsaac to GFR Pharma, and documents regarding common ownership of the GFR and McIsaac Distribution. The DEA also obtained the FDA's records regarding the two companies. [Govt. Exh. 20 at 1–3; Tr. 90–91]. All of the records that the DEA obtained related to the ephedrine and pseudoephedrine products. [Tr. 91].

56. In 2010, GFR had a shortage of 79,000 tablets. [Tr. 257]. They reported this shortage to Health Canada. [Tr. 258]. Health Canada did not cite GFR Pharma, however, they did make a recommendation on how the company could account for the loss. [Tr. 258]. Mr. Pierce stated that the loss was just a ''manufacturing loss.'' [Tr. 260].

57. On an unspecified date, Health Canada inspected GFR Pharma and noted the following concerns: (1) ''although only two GFR designated employees have access to raw bulk ephedrine (possess the physical keys), all 61 employees conceivably have access to ephedrine at other stages of production (i.e. blending, bulk tableting, packaging, as well as shipping);'' (2) record could not be found for certain inbound transportation shipments; (3) no records exist to quantify past destruction; and (4) there are conflicts between processing stages in GFR's records, namely the actual yield is less than the projected yield; and (5) ''GFR does not maintain a precursor access log. No record exists tracking personnel accessing stock either within the precursor cage, or within the overall warehouse.'' [Govt. Exh. 20 at 22].

58. Mr. Pierce testified that Health Canada would not renew its license if it found serious violations. [Tr. 271].

59. In Mr. Pierce's experience, he has dealt with Health Canada regarding licensure and inspection, including surprise inspection. [Tr. 252–53]. GFR has been inspected by Health Canada on three occasions. [Tr. 253]. GFR must re-apply for its licensure yearly and its license has been renewed by Health Canada every year. [Tr. 252–253]. The DEA was not informed of any citations by Health Canada of GFR. [Tr. 164].

60. The DEA reviewed Health Canada's records on the sale of the precursor product, 4 Ever Fit-Ephedrine Hydrochloride 8 mgs by GFR to various companies from January 6, 2009 to January 29, 2009. [Tr. 129; Govt. Exh. 20 at 42–44]. None of the companies listed in that report had addresses in the United States. [Govt. Exh. 20 at 42–44]. The DEA did not obtain any evidence that GFR Pharma marketed 4 Ever Fit as a weight loss product and sold it as such into the United States. [Tr. 173].

(1) Customs Seizure

61. During its investigation, the DEA found evidence that GFR Pharma was the source of ephedrine that a third party had purchased and attempted to ship illegally into the United States. [Tr. 86–87]

62. On or about January 27, 2010, U.S. Customs and Border Patrol seized three packages with suspicious labels at Seattle International Airport, Washington. [Tr. 86, 212]. The packages were en route to Phoenix, Arizona. [Tr. 86]. The sender listed on the packages was Better Bodies Nutrition. [Tr. 87, 217–18; Govt. Exh. 15 at 2; Govt. Exh. 20 at 6].

63. Better Bodies Nutrition is a company that sells nutritional supplements via the internet. [Govt. Exh. 15]. Better Bodies Nutrition Web site markets ephedrine and advertises the sale of the 4 Ever Fit Product. [Govt. Exh. 15; Tr.144]. Specifically, they have purchased the 8 mg ephedrine hydrochloride product. [*See* Tr. 143–44].

64. The products originated from GFR Pharma. [Tr. 87]. While, Better Bodies Nutrition is not a direct customer of GFR Pharma, GFR supplies to 4 Ever Fit, Ltd. who then sells to Better Bodies. [Tr. 275, 368]. Regardless, GFR has knowledge of where 4 Ever Fit sells its product. [Tr. 368].

65. The products were destined for a company called One Stop Nutrition in Phoenix, Arizona. [Tr. 113].

66. The shipping labels indicated that the packages contained ''vitamins.'' [Govt. Exh. 14; *see also* Tr. 214].

67. After customs observed the suspicious shipping labels, they opened the packages to confirm the contents. [Tr. 212–13]. Each box contained 48 bottles, labeled ''4 Ever Fit.'' [Tr. 215]. Each bottle contained 50/8 mg ephedrine tablets. [Tr. 215].

68. On February 4, 2010, DI Morgan, U.S. Postal Services, and a member of the Arizona Board of Pharmacy visited all three addresses listed on the seized packages and discovered all three were One Stop Nutrition Stores, which sold health and body supplements and vitamins. [Tr. 220–221]. In addition, all three stores shared parking lots with fitness clubs. [Tr. 221–222]. Each store had ordered one box, containing 48 bottles, of the 4 Ever Fit product. [Tr. 240].

69. The One Stop Nutrition stores were located in Scottsdale, Tempe, and Phoenix, AZ. [Tr. 222, 224, 225]. DI Morgan spoke with each of those store's owners, respectively, Justin Denis, Brian Kerry, and Matt Denis [Tr. 223, 224, 225]. Each of those individuals stated that they purchased the 4 Ever Fit product to replace a product called Vasapro, which was no longer available. [Tr. 223, 224, 226]. Each owner intended to sell 4 Ever Fit as a weight loss product. [Tr. 223, 225, 228].

70. While the Tempe and Phoenix One Stop Nutrition Stores were self-certified with DEA, Justin Denis had not self-certified his location in Scottsdale. [Tr. 231].

71. In addition, none of the One Stop Nutrition stores that DI Morgan visited had importer registrations nor did they fill out a Form 486 prior to their orders of 4 Ever Fit from Better Bodies Nutrition. [Tr. 232–233].

72. Similarly, Better Bodies Nutrition did not have a Canadian export license. [Tr. 115–16].

73. Mr. Pierce testified that he had no knowledge of Better Bodies Nutrition selling or trying to sell 4 Ever Fit into the United States. [Tr. 276]. When questioned whether GFR had done anything about its relationship with Better Bodies Nutrition to ensure that the improper shipment doesn't occur again, Mr. Pierce testified ''[w]e have no control over them buying the product from us and shipping it without our knowledge. [Health Canada] . . . has been informed'' and it is his understanding that they have dealt with Better Bodies to ensure that they don't attempt to ship into the United States and are familiar with the repercussions of that. [Tr. 362].

D. Other Entities

1. 4 Ever Health Distribution Ltd.

74. 4 Ever Heath Distribution Ltd. is a Canadian company owned by Richard Pierce. [Tr. 280].

75. 4 Ever Health Distribution distributes the 4 Ever Fit product in Canada. [Tr. 280].

2. 4 Ever Fit Companies

76. There are two 4 Ever Fit companies: 4 Ever Fit 2008 Ltd. (''4 Ever Fit''), a Canadian company, and 4EF Inc. d/b/a 4 Ever Fit USA (''4EF USA''), a United States company. [Respt. Exh. 4; Tr. 280–81].

3. 4 Ever Fit—Canada

77. Richard Pierce is also the President and CEO of 4 Ever Fit. [Tr. 252].

78. 4 Ever Fit sells sport supplement style products such as proteins as well as the 4 Ever Fit product. [Tr. 255, 280].

79. Mr. Pierce testified that he does not sell ephedrine products directly into the United States. [Tr. 268].

4. 4 Ever Fit—USA

80. 4EF Inc., d/b/a 4 Ever Fit USA (''4EF USA'') is a United States company. [Tr. 280–81].

81. It is owned by Richard Pierce, through a company called 4 Pharma, LLC. [Tr. 280].

82. Mike Schiefelbein is the president of 4EF USA. [Tr. 373]. It is currently based in Peoria, Arizona. [Tr. 373].

83. Mr. Schiefelbein has been in the sports nutrition supplement business for approximately 13 years. He has prior experience selling ephedrine as a dietary supplement when it was legal to do so in the United States. [Tr. 374–5].

84. 4 Ever Fit USA does not sell ephedrine products. [Tr. 374]. It only sells supplements, nutritional products, protein powders, amino acids, weight gainers, weight-management products to health stores and fitness facilities in the United States. [Tr. 281, 365, 374].

85. A small percentage of 4EF USA's business is end users. Most of their customers are brick-and-mortar retailers and distributors. [Tr. 374, 389]. Approximately 10–15% of its business is internet sales. [Tr. 391].

86. 4EF USA's products will be kept in the same warehouse as 4 OTC's products, however, the 4 OTC product will be kept separate in a cage. [Tr. 395]. In addition, 4OTC will have separate access logs and inventory logs than 4EF USA. [Tr. 395–6].

5. 4 Pharma, LLC

87. Richard Pierce owns 4 Pharma, LLC (''4 Pharma''). [Tr. 363].

88. 4 Pharma owns 4EF USA. [Tr. 280].

89. 4 Pharma also owns 60% of 4 OTC. [Tr. 364].

90. 4 Pharma will not be part of the distribution chain of ephedrine from GFR to 4 OTC, Inc. [Tr. 363].

6. Vasapro

Megapro is a U.S. company that sells Vasapro, an ephedrine HCL product. Megapro markets Vasapro as a bronchodilator expectorant. [Govt. Exh. 5; Tr. 144–45]. Specifically, Megapro's Web site states that the product is ''taken for the temporary respite of shortness of breathing, accumulation in the chest and wheezing because of bronchial asthma . . . [and it] also helps slime relaxation and empowers thin bronchial secretions to draining out bronchial tubes.'' [Govt. Exh. 5 at 1]. However, that Web site is also titled in large font ''Ephedrine Weight Loss Products.'' [*Id.*]. In addition, the left hand side of the page has links for other ''ephedrine weight loss products.'' [*Id.*]. The right hand side of the Web site contains the following statements:

c. ''Using Ephedrine To Burn Fat, Increase Strength and Muscle.''

d. ''Ephedrine Effects on Fat Loss and Muscle Growth . . . When administered, ephedrine noticeably stimulates the central nervous system, increasing the heart rate and has an overall heat producing (thermic) effect on most tissues in the body—this includes muscle and fat tissue, helping the user burn more body fat, as well as having stimulatory effect on other target cells.''

e. ''Ephedrine Protects Lean Tissue (Muscle) . . . Researches show that Ephedrine plus Caffeine combo protects lean tissue (muscle) while on reduced calorie diets.'' [*Id.*].

91. Mr. Pierce testified that Vasapro is the only competitor that he could think of for 4 OTC as he is not familiar with other companies selling ''the combinations.'' [Tr. 314].

7. Other Retail Sellers of Ephedrine Product

92. SupplementSource is a Canadian company that sells the 4 EverFit product via the internet. [Tr. 147–8; Govt. Exh. 8 at 1].

93. There are other companies that market ephedrine bronchodilators similar to how Megapro markets Vasapro. GorillaJack.com (''Gorilla Jack'') is a company that sells Kaizen Ephedrine HCL 8 mg via the internet. [Govt. Exh. 9 at 8]. Its Web site states that it will ship any of its products anywhere in the world as it is impossible for them ''to keep up with all the regulations/laws in every country.'' [Tr. 150; Govt. Exh. 9 at 4]. Gorilla Jack markets the Kaizen ephedrine product as an oral and decongestant yet also notes that the drug ''has strong metabolic boosting properties . . . [and] [d]espite its effectiveness as a . . . body fat reduction product, it can only be officially sold as an oral nasal decongestant.'' [Govt. Exh. 9 at 18]. There is no relationship between Gorilla Jack and GFR Pharma. [Tr. 163–4]. To the best of Mr. Pierce's knowledge, GFR Pharma does not sell to this company. [Tr. 279].

E. Respondent's Ownership and Operation

94. Kevin McIsaac signed 4 OTC's DEA applications. [Tr. 34].

95. Richard Pierce is the President and CEO of 4 OTC. [Tr. 252]. Mr. Pierce also testified that he is the majority owner of 4 OTC. [Tr. 279, 284]. He testified that he owns 4 OTC, Inc. through 4 Pharma LLC. [Tr. 364].

96. Mr. Schiefelbein owns fifteen percent (15%) of 4 OTC. [Tr. 35, 376].

Mr. Schiefelbein testified that he fully intends to comply with all state, local and federal regulations. [Tr. 380]. He also testified that he has no prior convictions. [Tr. 380]. Mr. Schiefelbein testified that he will oversee the day-to-day duties of 4OTC. [Tr. 392–3].

97. According to DI Quintero's investigation, Kevin McIsaac owns seventy percent (70%) of 4 OTC. [Tr. 34–35]. However, according to Mr. Pierce's testimony, Kevin McIsaac only owns ten percent (10%) of 4 OTC and Mr. McIsaac is not involved in the day-to-day operations. [Tr. 284]. If in fact, Kevin McIsaac only owns 10% of 4 OTC, then that leaves 15% of 4 OTC unaccounted for. [*See* FOF 103 (Mr. Schiefelbein owns 15%); FOF 102, 95 (Mr. Pierce owns 60% of the Respondent through 4 Pharma)]. Accordingly, I will not make a finding as to the actual ownership interest of Kevin McIsaac in the Respondent.

98. Mr. Schiefelbein informed DEA Diversion Investigators that 4 OTC intended to procure the ephedrine from McIsaac Distribution. [Tr. 31]. At the hearing, however, Mr. Pierce testified that GFR Pharma is the supplier of ephedrine for the Respondent. [Tr. 289].

99. Mr. Pierce testified that Kevin McIsaac will have ''nothing to do with the company,'' as he will be located in Canada and not in Phoenix. He also testified that he, Mr. Schiefelbein, and ''[their] quality control . . . office in Canada'' will be in charge of shipping the ephedrine from GFR Pharma down to Phoenix. [Tr. 296].

100. Mr. Schiefelbein stated that his sale of ephedrine would be conducted 100% via the internet. [Tr. 33].

101. Mr. Pierce testified that 4 OTC would not sell its product for any other purpose other than as a bronchodilator. [Tr. 277]. 4 OTC only intends to sell its product on a retail level to end users. [Tr. 393].

102. 4 OTC is kept separate from 4EF USA to avoid ''comingling of products and product categories.'' [Tr. 375].

F. The 4 OTC Product

103. The 4 OTC product will be sold as a combination of ephedrine and guaifenesin. [Tr. 302; Resp. Exh. 5]. The product will come in a 12.5 mg ephedrine/200 mg guaifenesin formula, a 25 mg ephedrine/400 mg guaifenesin formula, and a 12.5 mg ephedrine/400 mg guaifenesin formula. [Tr. 306–07]. Mr. Pierce is not familiar with any other company selling a 12.5 ephedrine/400 mg guaifenesin combination product in the United States. [Tr. 308].

104. Mr. Pierce testified that he inherited these formulas and that his understanding of the reasons for having

the different kinds was so that there was a regular and an extra strength product. [Tr. 306–7]. His consultant testified that he has mostly seen a 12.5/200 ephedrine/guaifenesin product and less a 25/400 mg combination product. [Tr. 423]. He has never seen a 12.5/400 mg product. [Tr. 423–4].

105. Neither the Respondent nor its owners have any experience in dealing with guaifenesin. [Tr. 305]. GFR Pharma currently produces a single entity product in Canada. [Tr. 303–4].

106. Mr. Pierce believes his quality-control department contacted the FDA about bringing this product into the United States.[11] [Tr. 307].

107. Mr. Pierce testified that he believes that these products meet the FDA's criteria as far as quantities of listed chemical products allowed based on Mr. McIsaac's representation to him that that was the case when he purchased the company. [Tr. 309–11].

108. GFR will manufacture the ephedrine/guaifenesin product in the same facility that it manufactures the 4 Ever Fit product. [Tr. 311–2].

109. To make the 4 OTC product GFR must increase the size of the tool that currently makes its single entity ephedrine product to account for the additional excipient, guaifenesin. It must also add more binders and fillers to hold that product together. GFR will then quality control that product. [Tr. 312–14].

G. Marketing and Sale of the Respondent's Product

110. Throughout the hearing, representatives of the Respondent maintained that it would only sell its product as a bronchodilator in the United States. Indeed, Mr. Pierce testified that 4 OTC would not sell it for any other purpose. [Tr. 277, 290–91]. Mr. Pierce testified that the guaifenesin is intended to bring up the mucous in the body and help loosen it up. [Tr. 304].

111. During his initial interview with DIs Quintero and McCormick in July of 2008, Mr. Schiefelbein gave the DI's Standard Operating Procedures (''SOPs'') for the Respondent. [Tr. 29, 33]. Those SOPs included a brand label for the 4 Ever Fit product. [Tr. 34]. The Respondents current SOPs contain the same label without the words ''4 Ever Fit.'' [Tr. 47–48; Respt. Exh. 5].

112. The label that Respondent intends to use for its product reads ''eases breathing for asthma patients by reducing spasms of bronchial muscles. For the temporary relief of bronchial asthma.'' [Resp. Exh. 5 at 1; Tr. 290].

113. Mr. Pierce testified that 4 OTC had yet to devise a ''brand name'' that would go on the actual labels. He stated that the company did not intend to place the 4 Ever Fit logo on the package of the 4 OTC product. He stated that ''we're just going to sell it as the name ephedrine hydrochloride.'' [Tr. 299–301].

114. Mr. Schiefelbein testified that 4 OTC will not use the customer base of 4 Ever Fit to sell the ephedrine product. [Tr. 377]. However, when DI Quintero asked Mr. Schiefelbein for a customer list, he was unable to provide one. [Tr. 28–29].

115. Mr. Pierce testified that he did not conduct any market research, investigating the potential customer base for the 4 OTC product, prior to his purchasing of his interest in 4 OTC. He also testified that while he believes Mr. McIsaac conducted such research, he has not seen any of that research. [Tr. 324–5]. When asked how he knew that customers would need ephedrine to be treated for asthma and would be inclined to purchase that product over the internet, he responded ''Well, considering the statistics on how many people buy off the Internet, it seems that more people are interested, especially if people are looking for these type [sic] of products, to order them off the Internet. It's a very convenient method.'' [Tr. 326–7]. He later testified that because 4 OTC has not done market projections, they don't know the quota that they would seek from the DEA. [Tr. 366–7].

116. Mr. Pierce testified that there is a need for an ephedrine bronchodilator in the United States. [Tr. 282]. He stated that need is the helping of people with asthma. [Tr. 282].

117. Mr. Pierce also testified that certain persons may want to buy this product through the internet, as opposed to going to a pharmacy or convenience store, because it is more convenient to do so. [Tr. 282].

118. Mr. Schiefelbein testified that he was a party to the decision to initially move forward with the 4 OTC venture. [Tr. 384]. He testified that the decision was made because ''there may be a gap and a need in terms of . . . the asthma-related conditions.'' [Tr. 384–85]. When asked why an individual would chose to treat their asthma with the 4 OTC product versus a prescription medication, Mr. Schiefelbein testified that the 4 OTC product would serve various markets where individuals may not be able to afford medication for an asthma condition. [Tr. 380]. However, Mr. Schiefelbein did not calculate that there was an under-supply of ephedrine in the U.S. market. [Tr. 386].

119. When Mr. Pierce was asked whether the intended market for the 4OTC product was ''anyone who wishes to buy ephedrine products on the Internet'' he responded ''well . . . I guess it is to people who will use for a bronchial dilator, but yes.'' He then stated that 4 OTC has no mechanism by which to know whether, in fact, the product will be used for that purpose. [Tr. 365]. He stated that he would just market it to people who need it directly as a bronchodilator for bronchial asthma. [Tr. 302].

120. Mr. Pierce also stated that he doesn't anticipate any of the customers who purchase his dietary supplements would also purchase the 4 OTC ''unless they have a condition that requires the product.'' [Tr. 327].[12]

121. When asked whether it would be better to market a single entity ephedrine product, Mr. Pierce testified that the combination was that which he ''inherited with the company . . . [He] didn't want to change the direction of what [they were] doing.'' [Tr. 328].

122. When asked about other bronchodilators, Mr. Pierce was unaware. For example, he was unaware of the products Primatene and Bronkaid. [Tr. 334]. In addition, Mr. Pierce was unaware that ephedrine products are sold to convenience stores in the United States. [Tr. 334].

1. Website

123. Mr. Pierce testified that 4 OTC does not currently have a Web site. [Tr. 289]. However, he also testified that 4 OTC does not plan to market its product on the 4 Ever Fit Web site. [Tr. 293]. His testimony indicates that the company has not yet finalized how they will advertise the product. [*See* Tr. 329 (stating that the product could be located by Google search or elsewhere depending on ''where we could advertise the product. We'd have to confirm that'')]. Mr. Pierce did testify that at some point, 4 OTC will have a Web site separate from the 4 Ever Fit Web site. [Tr. 364]. 4 OTC will also not advertise 4 EF USA's products on its Web site. [Tr. 379].

124. Mr. Pierce testified that the product will be marketed as a hard tablet, and not a gel cap. [Tr. 301].

[11] The record contains no further information about this contact.

[12] Given Mr. Pierce's prior testimony about the lack of research he reviewed or conducted regarding the use of ephedrine as a bronchodilator in the United States, I find most, if not all, of his testimony as to why the Respondent's product would be purchased and used unfounded and incredible.

2. Packaging, Labeling, and Sale of the 4 OTC product

125. Mr. Pierce correctly identified and testified that he is aware of the retail daily and monthly sales limits for ephedrine in the United States. [Tr. 291].[13] He stated that 4 OTC plans to sell twenty-four (24) tablets in one carton. [Tr. 292]. Therefore, to exceed the daily limit, a person would have to purchase twelve boxes. He testified that that is a large order and that he doesn't anticipate someone ordering that amount. [Tr. 292].

He testified that the product would be sold as a hard tablet in blister packs in a box. [Tr. 301]. The products packages will be labeled as follows:

a. On the Front Cover:

i. EPHEDRINE HYDROCHOLORIDE (24 tablets)

ii. Eases Breathing For Asthma Patients By Reducing Spasms Of Bronchial Muscles for the Temporary Relief of Bronchial Asthma.

iii. Contains: Ephedrine HCl ____mg, Guaifenesin ____mg per tablet

b. On the Back Cover:

i. Under Drug Facts

1. Active Ingredients

a. Ephedrine HCl____mg……..bronchodilator

b. Guaifensin____mg……expectorant

2. Uses

a. For temporary relief of bronchial asthma

b. Eases breathing for asthma patients by reducing spasms of bronchial muscles

c. Helps loosen phlem [sic] (mucus) and thin bronchial secretions to make coughs more productive.

3. Warnings

a. Do not use this product unless a diagnosis of asthma has been made by a doctor. Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostrate gland unless directed by a doctor. Do not use this product if you have ever been hospitalized for asthma or if you are taking any prescription drugs for asthma unless directed by a doctor. Do not continue to use this product, but seek medical assistance immediately if symptoms are not relieved within 1 hour or become worse. Some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your doctor. A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by a fever, rash or persistent headache, consult your doctor. DRUG INTERACTION PRECAUTION: Do not use if you are now taking a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's' disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor before taking this product.

c. On the top cover:

i. Directions

a. Adults and children 21 years of age and over: oral dosage is 1 tablet every 4 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor. Do not exceed recommended dose unless directed by a doctor.

Children under 21 years of age: Consult a doctor. [Resp. Exh. 5].

H. Respondent's SOPs

126. The SOPs that the Respondent introduced at the hearing are distinct from those that the Respondent first gave to the DEA. The Respondent revised its SOPs after the Order to Show Cause was issued in this proceeding. [Tr. 298].

1. SOPs Regarding State Laws

127. Some states regulate ephedrine more stringently than the federal government. [Tr. 63]. For example, some states have scheduled ephedrine and, therefore, a firm would need a registration, certificate, or a license to sell an ephedrine product in that state. [Tr. 63]. In some cases—a state will send a ''cease and desist'' letter to a firm selling ephedrine via the mail. [Tr. 69].

128. In its SOPs, the Respondent via chart addresses various state requirements, including the maximum number of grams/packages permitted to be sold per transaction, day, week, and month; [14] whether there are limitations on the combinations of ephedrine/guaifenesin that may be sold; how long the entity must keep records; the minimum age for the purchaser; and whether ID, signature, employee training, and state licensure are required. [Respt. Exh. 10 at 27].

129. In addition, the SOPs address in bullet format each state's requirements. [Resp. Exh. 10 at 20–26]. For example, the SOPs state that in Alabama a purchaser must ''sign special electronic or paper register maintained for two years. These records must be maintained for at least 180 days.'' [Resp. Exh. 10 at 20].

130. Under the bulleted outline for New Hampshire, the SOPs only state ''comply with federal regulations.'' [Resp. Exh. 10 at 23]. When Mr. Pierce was questioned about this SOP he agreed that he could be pretty certain that New Hampshire would allow 4 OTC to sell ephedrine into the state, so long as they were compliant with federal regulations. [Tr. 340]. Later in the SOPs, however, on the chart for state requirements, there is a ''Y'' under the column marked ''state license'' corresponding to the state of New Hampshire. [Resp. Exh. 10 at 29].

131. In addition, there are several states where the Respondent is not likely to get licensed. [*See* Govt. Exh. 19C (Arizona); Govt. Exh. 19D (Arkansas); Govt. Exh. 19M (Iowa); Govt. Exh. 19J (Kansas); and Govt. Exh. 19N (Louisiana)]. However, that likelihood is not included in the Respondent's SOPs. [Tr. 341–3; Resp. Exh. 10]. Mr. Pierce agreed that state law restrictions would preclude 4 OTC from lawfully handling ephedrine products in Montana, New Mexico, Michigan, North Carolina, and Louisiana. [Tr. 341–46].

132. With respect to the requirements for the State of Michigan, the Respondent's SOPs indicate that state license is required, the maximum number of packages that may be sold per transaction is 2, the maximum number of grams of the 4 OTC product that can be sold per month is 9 and cannot exceed a 25/400 ephedrine/guaifenesin combination, the Respondent must keep records for 6 months, the minimum age for purchase is 18, and both photo ID and signature are required. [Resp. Exh. 10 at 28]. However, the Respondent's SOPs overlook the fact that Michigan expressly prohibits the internet sale of ephedrine into its territory. [Govt. Exh. 19–P at 5].

133. With regard to additional state regulations, not contained in the Respondent's SOPs, Mr. Pierce testified that ''we are relying on our attorney's to complete our due diligence on that, once we move to the next level.'' [Tr. 347–8].

134. He also stated that SOPs are always a ''work in progress.'' [Tr. 357]. Although some states made ephedrine products Schedule IV or V controlled substances, Mr. Pierce was unfamiliar with the concept of scheduled substances. [*See* Govt. Exh. 19S

[13] However, the initial 4 OTC SOPs incorrectly recounted the sales limitations. [Tr. 35–36]. The current SOPs correctly note the sales limits to retail (i.e. mail order) customers. [Resp. Exh. 10 at 16].

[14] In describing the permissible number of packages that may be sold, however, the Respondent does not identify what combination ephedrine/guaifenesin product it is referring to, i.e. 12.5/200, 25/400, or 12.5/400. [*See* Respt. Exh. 10 at 27].

(Missouri; Govt. Exh. 19AA (Oklahoma); Govt. Exh. 19Z (Ohio); Tr. 345].

135. At the hearing, Mr. Pierce appeared unaware of an Arizona Board of Pharmacy requirement that the Respondent obtain a state license as an ephedrine wholesaler prior to importing ephedrine into the state, until the Government's counsel pointed the need for it on cross-examination. [Tr. 371].

136. At the time of the hearing, the Respondent did not have such a license. [Tr. 443]. Mr. Mudri, the Respondent's expert later testified that there seems to be some confusion as to whether that is in fact required. [Tr. 424]. The Respondent later acquired that license. [Resp. Exh. 12].

137. Mr. Mudri testified that he cannot speak for the accuracy of the Respondent's SOPs regarding state laws. [Tr. 426].

138. In light of the various state regulations, Mr. Pierce agreed that he is not certain how many states the Respondent will be able to obtain licensure in. [Tr. 351–52]. In addition, Mr. Pierce has not projected in which states there would be the most potential to sell. [Tr. 352].

139. He also stated that his decision to sell via the internet may be affected by state licensure requirements. [Tr. 369].

2. 4 OTC's SOPs Regarding DEAs Regulations

140. When the Respondent first presented its SOPs to DI Quintero, those SOPs stated that the ephedrine retail sales limit was 24 grams and the ephedrine limit for record-keeping was 1 kilogram. [Tr. 35–36].

Currently, the Respondent's SOPs state the following with regard to complying with the DEA's regulations:

a. Warehouse Security

i. All Schedule listed chemicals will be stored in a caged area that is locked and will have limited access to designated employees [15] of the company.

ii. The doors to the cage will be self-locking, self-closing doors.

iii. Access to the cage will be recorded in an access log.

iv. In working hours—the caged area is protected by surveillance and guard station, and in non-working hours by a central station alarm service with a duty to respond and notify local law enforcement to respond.

v. All schedule listed chemical products ''are immediately placed within the storage area upon receipt or returned to the storage area when not being transported.'' [Resp. Exh. 10 at 2–3].

b. Employee Hiring:

i. That the company will only hire employees without a criminal or drug related criminal background.

ii. Backgrounds and drug tests will be conducted initially and then randomly afterwards.

iii. Employees will be trained in all facets of dealing with list I chemicals, including self-certification and downstream distribution requirements for the company's customers.

iv. The company has established a reporting procedure similar to 21 CFR 1301.91 for reporting diversion. [Resp. Exh. 10 at 5–6].

c. Importation

i. The company must apply for an importation quota annually via Form 250 (included in SOPs).

ii. The company must either provide information to establish a ''regular business relationship'' with its Canadian supplier or notify the DEA 15 days prior to any importation via form 486 (included in SOPs). [Resp. Exh. 10 at 8].

d. Marketing Sales and Shipping

i. The company must identify the party who is receiving the product, such as a driver's license, and verify the existence and validity of the customer.

ii. In addition, the company will obtain a second form of identification from the customer that corroborates the driver's license.

iii. The company will adhere to state by state restrictions regarding the sale of the ephedrine chemical drug product.

iv. The company will ship by U.S. Mail or other common carrier.

v. ''While temporarily stored in preparation for shipment outside of the caged area within Freeport Logistics, the product will be under constant observation by employees of the company and shipping containers will be unmarked, not indicated [sic] they contain [schedule listed chemicals] to guard against in-transit losses.''

vi. The company shall comply with FDA and FTC regulations regarding the advertising of over the counter drugs. The advertising will be truthful and non-misleading. [Resp. Exh. 10 at 15–18].

e. Recordkeeping

i. To keep reports, inventories and sales of schedule listed chemical products consistent with Part 1310 of the Code of Federal Regulations. [Resp. Exh. 10 at 31].

141. When Mr. Pierce was questioned about how he intended to comply with the DEA's 486 Form requirement that the Respondent inform DEA who the product is going to be sold to before importation, the Respondent answered ''One of the ways, we could presell the product and take orders, showing that we have orders from customers, and then bring the product in.'' [Tr. 359]. He also testified that they could do ''auto ship, if people wished to sign up for a monthly shipment.'' [Tr. 360].

142. Throughout the hearing, Mr. Pierce and Mr. Schiefelbein stated their intent to comply with all state and federal regulations that govern the Respondent's practice. [Tr. 293, 358, 359, 372, 380, 395–96].

143. Mr. Mudri testified the Respondent's SOPs adequately address the DEA's recordkeeping requirements. [Tr. 430–1].

144. Mr. Mudri testified that he believes that 4 OTC's management has an understanding of DEA regulations and that the company's SOPs ''are a good start with regards to operations.'' He clarified, ''I think that maybe down the road there may have to be some things added.'' [Tr. 413].

145. Mr. Mudri was unfamiliar with the DEA's requirement that any person who desires to sell ephedrine via the internet must self-certify. [Tr. 435–6].[16]

I. Letter from Respondent to DEA Regarding its DEA Application.

146. On February 19, 2009, the Respondent, through counsel, sent a letter to DEA Diversion Group Supervisor Helen Kaupang. Therein, the Respondent identified as the Government's primary concerns the internet sale of ephedrine and the lack of proper identification of its customers. [Govt. Exh. 11 at 1].

147. The Respondent explained that it had developed SOPs to ensure full compliance with federal and state laws, and that all of the employees and management of both the Respondent and the Respondent's affiliate, 4 Ever Fit, are familiar with the SOPs. [Govt. Exh. 11 at 2].

148. The Respondent stated ''[o]ther companies are selling and distributing ephedrine products on the Internet. These companies such as Mega-Pro and their Vasapro product-obtained

[15] The term employee is defined in the SOP as ''all persons that perform any business related activity at the facility or regarding the ephedrine chemical drug product.'' [Respt. Exh. 10 at 2].

[16] To keep apprised of DEA regulations, which Mr. Mudri admits is a ''difficult task,'' he does his best to read the laws that have changed, including the Combat Meth Act, monitors show cause hearing, and keeps up with what's going on within DEA and the community. [Tr. 402]. Mr. Mudri admitted that there have been several changes to the list I chemical laws since he served as Chief of the Domestic Chemical Operations and since he left DEA in 2001. [Tr. 407]. He has served as a consultant for businesses that handle listed chemicals, although his practice consulting importers has been somewhat limited. [Tr. 403].

controlled substance licenses which included Internet sales and have had these licenses renewed.'' [Govt. Exh. 11 at 2].

149. The Respondent then stated that ''[b]ecause these other internet companies exist, the DEA must be satisfied that there are ways to properly identify customers and comply with Federal and State controlled substance laws.'' [Govt. Exh. 11 at 2].

150. With regard to the Respondent's prior experience in handling controlled substances, the letter states ''4OTC has operated a business in Canada under the name of 4 EverFit since 2001. 4 OTC's management owned McIsaac Distribution, Ltd., who was the distributor of their products both in Canada and internationally until 4OTC formed a partnership with GFR Pharma Ltd.'' [Govt. Exh. 11 at 2].

151. Respondent stated that ''4OTC formed a partnership with GFR Pharma Ltd. in 2008 . . . [and] GFR will be the exclusive manufacturer of products distributed by 4OTC in the United States.'' [Govt. Exh. 11 at 2]. The Respondent further explained that ''[k]ey personnel involved in handling precursor substances for GFR Pharma include Richard Pierce the CEO of GFR . . . [and] Maribel Aloria [who] is Vice President, Quality Control/Research & Development for GFR.'' [Govt. Exh. 11 at 2].

152. With regard to the list of potential customers, the Respondent provided that ''4OTC does not currently have any customer list. 4 OTC will be happy to provide a customer list after approval of their applications as such information becomes available.'' [Govt. Exh. 11 at 3].

IV. Statement of Law and Discussion

A. Position of the Parties

1. Government's Position

The Government asserts that the Respondent's application should be denied on the following basis: (1) that there has been a drop in the ephedrine market; (2) 4 OTC's Canadian affiliate and potential competitors sell ephedrine for non-legitimate purposes; (3) 4 OTC has not established any basis to show a legitimate ephedrine market in the United States; (4) 4 OTC's Canadian companies lack relevant experience; (5) 4 Ever Fit ephedrine is sold to convenience stores in the United States; (6) the Respondent has failed to consider the state laws pertaining to ephedrine; (7) 4 OTC's Canadian companies have violated Canadian regulatory provisions; (8) 4 OTC's decision to change its logo after the OTSC indicates that if the Respondent's registration had been granted it would have been marketed in a name that implied ephedrine's illicit use; and (9) Respondent's failure to notify DEA of its proposed address and failure to obtain a lease and proper security for a new lease indicates the Respondent's application is fraught with problems. [Government' Proposed Findings of Fact and Conclusions of Law ''(Govt. Brief) at ii; 44].

Specifically, the Government argues that ephedrine sales have substantially declined in both the overall over-the-counter market and particularly for mail orders. The Government thus questions why the Respondent would enter a market that is clearly declining. [Govt. Brief at 37]. Likewise, the Government avers that the market for 25/400 mg ephedrine product that 4 OTC seeks to market is declining, the pseudoephedrine market is significantly higher than the ephedrine market, and that the 12.5/400mg ephedrine product that 4 OTC seeks to market does not even exist in the U.S. market. [Govt. Brief at 37–38].

The Government argues that 4 OTC's competitors, Vasapro and Kaizen, sell ephedrine for other than a legitimate medical purpose. The Government alleges that the Respondent does not dispute it intends to compete with Vasapro and that Vasapro clearly markets its product ''to increase strength and muscle.'' [Govt. Brief at 38].

The Government then asserts that Kaizen was one of the 4 Ever Fit's competitors in Canada, and that company advertised ephedrine as a ''supplement source.'' [*Id.*].

The Government thus argues that there is a market for illegitimate uses of ephedrine, i.e. as a dietary supplement. [*Id.* at 39]. The Government further asserts that those facts in addition to the fact that the Respondent was unaware of two other brands of ephedrine, Primatene and Bronkaid, indicate the Respondent's product is not destined for any legitimate market. [*Id.* at 40].

Next, the Government asserts that the Respondent only speculates as to who would purchase the product, and hence has no idea what its quota would be. Indeed, the company never calculated whether there was an undersupply of ephedrine in the United States. [*Id.* at 39–40].

The Government then argues that GFR Pharma has never produced an OTC product for medical use and thus lacks the requisite experience to be 4 OTC's supplier. [*Id.* at 40–41]. The Government states that it is very apparent that the Canadian company's customer base is not composed of those who purchase ephedrine for asthma treatment. [*Id.* at 41].

Next, the Government argues that GFR does not have control over its customers, specifically 4 EverFit, and that it should have taken steps, including refusal to sell ephedrine to Better Bodies Nutrition as a result of that company's attempted illegal shipment into the United States. [*Id.* at 41–42]. The Government asserts that the Respondent ''gives DEA no assurance that 4 OTC would be responsible for its customers.'' [*Id.* at 42].

In addition, the Government argues that the Respondent is unfamiliar with the state laws that would govern its practice. Specifically, it asserts the Respondent's SOPs fail to note that the Respondent would be unable to obtain licenses in states where ephedrine is a controlled substance or required to be sold only by a pharmacy, and that Washington has a number of restrictions for retail stores that sell ephedrine that may preclude the Respondent from acquiring an ephedrine license. [*Id.* at 42–43]. The Government concludes that the Respondent's lack of awareness of state requirements renders it unable to even ''guestimate'' as to its actual customer base. [*Id.* at 43].

Next, the DEA argues that both McIsaac Distribution and GFR violated various Canadian laws, including McIsaac's selling of ephedrine to customers whose addresses could not be confirmed, and failure to report suspicious sales. The DEA argues that despite Health Canada never taking any civil or criminal action against GFR, 4 OTC's supplier, these past actions should be considered as negative experience in distributing List I chemicals. [*Id.*].

The Government also finds it significant that the Respondent amended its SOPs to correct errors regarding DEA's requirements, specifically an outdated sales limit of 24 grams and a confusion of recordkeeping versus sales limits. [*Id.* at 44].

The Government then argues that the Respondent's decision to changes its ephedrine package label to remove the ''4 Ever Fit'' logo after the Order to Show Cause was issued indicates that if the Respondent's registration had been granted then the Respondent would have been marketing ephedrine under a brand name ''that implied ephedrine's illicit use and had no relation to legitimate use.'' [*Id.*].

The Government further argues that the Respondent's changing of its registered address and failure to obtain a lease and security for a new lease reflects that its ''application process

continues to be fraught with problems and unresolved issues.'' [*Id.*].

The Government concludes by stating the Respondent has not provided any evidence justifying its reason for entering the ephedrine market in the U.S., which the Government argues is declining. It argues all evidence indicates that the Respondent's ephedrine is destined for customers who use it for weight loss and energy and other ''illicit purposes.'' [*Id.* at 45].

The Government argues that the Respondent's experience is much too involved with marketing ephedrine for illicit uses and consequently its lack of experience in the U.S. market, exacerbated by this negative experience in Canada, forms a basis for denying its application. [*Id.* at 46]. ''4 OTC is not prepared to market ephedrine legally and has not established that its customers would purchase ephedrine for legitimate medical reasons.'' [*Id.* at 47].

2. Respondent's Position

The Respondent argues that granting its importation application is ''well within the public's interest.'' [4 OTC's Proposed Findings Of Fact, Conclusions Of Law, And Argument (''Resp. Brief'') at 2].

First, the Respondent argues that ''there exists a strong market'' for its ephedrine product, ''allowing asthma sufferers an option to obtain relief without having to obtain a prescription.'' [*Id.* at 2]. The Respondent cites to the FDA monograph that permits the use of ephedrine for bronchial and asthma related conditions. [*Id.* at 1 (citing Cold, Cough, Allergy, Bronchodilator Products, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Final Monograph for OTC Bronchodilator Products, 51 FR 35,326 (1986) (codified at 21 CFR Part 341)].

The Respondent then argues that it has effective controls against diversion so as to render its registration in the public's interest. [Resp. Brief at 7–8]. Specifically, it states that its facility has adequate security, as DI Gary Linder, ''said it was okay.'' [*Id.* at 8 (citing Tr. 207)]. In addition, Mr. Mudri, the Respondent's consultant, agreed that those security measures were more than adequate. [*Id.* at 8]. The Respondent then states that it has adequate systems for monitoring the receipt, distribution, and disposition, of List I chemicals in its operations'' as outlined in its SOPs, which also evidence the ''sophistication and effectiveness of 4 OTC's security and anti diversion systems.'' [*Id.*].

In this same discussion, the Respondent addresses Canada's citations of McIsaac Distribution, and states that ''its principals and its employees have not been involved in excessive or suspicious sales of ephedrine products.'' [*Id.*]. To support this argument, the Respondent argues that these transactions were legal transactions and made before Mr. Pierce acquired assets of McIsaac. [*Id.* at 8–9]. The Respondent also argues that GFR had no knowledge of the shipment by Better Bodies of 4 Ever Fit into the United States and has not been cited by Health Canada, that the DEA is concerned about mere observations [17] by that agency. [*Id.* at 9–10].

Next, the Respondent argues that it is in compliance with federal and state laws and has demonstrated that it will continue to comply with those laws. [*Id.* at 10]. Specifically, it states that it has yet to import ephedrine, or market its proposed ephedrine products, and regularly consults with regulatory counsel and an expert in DEA regulations. [*Id.*].

The Respondent asserts that it has developed a formula and label that is fully compliant with the FDA's requirements for over-the-counter products. In addition, the Respondent emphasizes that ''the 4 OTC ephedrine product would *not* be used for weight loss or body building.'' [*Id.* at 12 (emphasis in original)''].

As for compliance with state laws, the Respondent states that it has obtained an Arizona Non-Prescription Drug Permit and its SOPS ''contain a comprehensive summary of state variations, evidencing [its] intent to comply with all state and local laws.'' [*Id.* at 13]. It further states that ''it will work with its attorneys and expert consultant to update its SOPs to include any changes to state regulations that may have occurred in the interim.'' [*Id.* at 13].

Next, the Respondent notes that none of its officers or employees have any prior convictions relating to ephedrine or any other controlled substance or chemical and that this factor weights in favor of the Respondent's registration. [*Id.* at 14]. The Respondent also points out its stringent hiring policy which will screen future employees to determine whether any such convictions exist. [*Id.*].

The Respondent emphasizes Mr. Pierce's experience in handling ephedrine as weighing in favor of its registration. The Respondent states that Mr. Pierce has ''*extensive* experience in dealing with ephedrine having manufactured ephedrine since 2004 . . . as well as retail experience sufficient to warrant registration in the United States.'' [*Id.* (emphasis in original)]. The Respondent also emphasizes GFR's separate Quality Control department and the fact that it has no significant violations of Canadian law pertaining to the manufacture and sale of ephedrine. [*Id.* at 14–15].

Last, the Respondent argues that there is a legitimate need for its product in the United States, as the FDA recognizes its use as an OTC bronchodilator. [*Id.* at 15–16]. Further, the Respondent argues that the amount of due diligence it has put forth thus far justify its registration. [*Id.* at 16].

The Respondent then addresses the DEA's diversion concerns, and states ''the Government did not proffer any specific statistics, data or evidence, nor did it present an expert witness, to show that the type of ephedrine combination product that 4 OTC intends to use can readily be used in the production of methamphetamine . . . or that this specific combination-ingredient product actually does show up in clandestine labs.'' [*Id.* at 16]. In addition, the Respondent argues that the Government failed to demonstrate that products marketed for off label uses, i.e. for mental alertness and weight loss, are diverted for methamphetamine production. The Respondent adds that off-label marketing is within the jurisdiction of the FDA and not the DEA. [*Id.* at 17]. ''The Government did not show that ephedrine products marketed for weight loss appear in 'illicit traffic in the United States.' '' [*Id.*].

Next, the Respondent addresses its failure to produce a customer list at the time of application. It states that such is not required by law but instead is only required to be produced 15 days prior to importation. The Respondent then argues that if the DEA desired to impose a requirement on applicants that they provide a customer list at the time of application, it would have to use notice and comment rulemaking to do so. [*Id.* at 18–20]. In addition, the Respondent argues that the reason it did not provide such a list is because it was non-operational at the time of application, and viewed soliciting sales of a DEA regulated product without proper registration as possibly illegal. [*Id.* at 20]. The Respondent assures, however, that it will provide a list of customers on its DEA 486 form as well as in the monthly sales reports that it provides to DEA. [*Id.* at 21].

The Respondent thus concludes that based on its arguments and the findings

[17] The Respondent argues that an observation report ''simply recommends improvements and is not considered a citation.'' [*Id.* at 10].

of its expert, that its registration would be consistent with the public interest. [*Id.* at 22–23].

B. Statement of Law and Analysis

1. Rulemaking

In 2006, via the Combat Methamphetamine Epidemic Act (''CMEA''), Congress amended 21 United States Code section 952(a)(1) to read, ''it shall be unlawful to import into the United States . . . ephedrine, pseudoephedrine, and phenylpropanolamine . . . except such amounts . . . as the Attorney General finds necessary to provide for medical, scientific, or other legitimate purposes.'' [21 U.S.C. 952(a)(1) (2006)].

Subsequently, the DEA promulgated regulations pursuant to the new statutory amendments. In a 2010 preamble to its final rule, the agency stated that via 952(a)(1), ''Congress essentially imposed the same requirements for importation of ephedrine, pseudoephedrine, and phenylpropanolamine as are imposed on narcotic raw materials—crude opium, poppy straw, concentrate of poppy straw and coca leaves.'' [75 FR 4,973 (DEA 2011)].

Accordingly, pursuant to DEA precedent as to the registration of importers of crude opium and poppy straw under 952(a)(1), there is a rulemaking aspect to this proceeding that shall be addressed. Specifically, to permit the Respondent's importation, the DEA must issue a rule finding that the Respondent's product is necessary to provide for medical, scientific, or other legitimate purposes in the United States. [See 5 U.S.C. § 556(d); Johnson Matthey, Inc., 67 FR 39,401, 39,401 (DEA 2002)]. Because the Respondent is the proponent of such rule, it bears the burden of proof. [*Johnson Matthey,* 67 FR at 39,402; *see also* Penick Corporation, 68 FR 6947, 6948 (DEA 2003)].

a. Medical, Scientific, or Other Legitimate Purpose

The Controlled Substances Act (''CSA'') does not define ''medical, scientific, or other legitimate purposes'' as that phrase is used in 952(a)(1). Instead, the statute gives authority to the Attorney General to find whether an import is necessary for those purposes. [21 U.S.C. 958(a)(1)]. The Attorney General delegated that authority to the Administrator of the DEA, who delegated the authority to the Deputy Administrator of the DEA.[18] Therefore, on its face, the statute grants significant deference to the DEA in determining not only what those purposes are, but also, whether an import would satisfy those purposes. [Zuber v. Allen, 90 S. Ct. 314 (1969) (finding that ''defining of a particular statutory term is a function that should, in the first instance, be left to the appropriate administrative body'')].

While the DEA has not formally defined how 952(a)(1) shall be interpreted in the context of the importation of ephedrine, in its final rule issued in 2010 removing the recordkeeping thresholds for the List I chemicals pseudoephedrine and phenylpropanolamine, the agency described some of ephedrine's licit purposes. It stated, ''ephedrine, pseudoephedrine, and phenylpropanolamine all have therapeutic uses in both over-the-counter and prescription drug products. Ephedrine is lawfully marketed under the Federal Food, Drug, and Cosmetic Act as an ingredient in nonprescription (''over-the-counter'' (OTC)) drugs as a bronchodilator for the treatment of asthma. Ephedrine is also available as a nonprescription product in combination with the active ingredient guaifenesin, which is an expectorant.'' [75 FR 38,915]. The DEA also described some of the illicit purposes for ephedrine. None of those purposes, however, included the use of an ephedrine product as a dietary supplement. The purpose for which 4 OTC, Inc. intends to import ephedrine into the United States was a highly contested issue in this proceeding. The Respondent maintains that it intends to import finished form ephedrine, specifically a guaifenesin/ephedrine combination product, into the United States for use as a bronchodilator. As indicated by recent DEA publications, this purpose is a legitimate one. [See 75 FR 38,915 (DEA 2010)]. However, the Government argues that the Respondent instead intends to serve the dietary supplement market with its combination product, despite its assurances that its product will be lawfully marketed in accordance with FDA law.

Nevertheless, it is the Respondent that bears the burden of proving the purpose for its proposed import. Here, the Respondent has failed to meet this burden. Although the Respondent's representatives made assurances throughout the hearing that it intends to import ephedrine for use as a bronchodilator, the evidence in this record is inconsistent with that intent.

Specifically, the Respondent was generally unfamiliar with the bronchodilator ephedrine market. Indeed, Mr. Pierce testified that he conducted no market research on the use of an ephedrine/gauifenisen as a bronchodilator in the United States. [FOF 116].[19] Yet, he speculated that ''there is a need for an ephedrine bronchodilator in the United States . . . and that need is helping people with asthma.'' [FOF 92; *see also* 117]. As a result of Mr. Pierce's failure to research the basis for that conclusion, I found that most if not all of his testimony regarding why the Respondent's product would be purchased and used speculative. [FOF 121, n. 13].

Further, while Mr. Schiefelbein testified that the decision was made for the Respondent to sell its product because ''there may be a gap and a need in terms of . . . the asthma-related conditions,'' he otherwise offered no evidence as to the basis for his inference that such a gap may exist. [FOF 119]. In addition, despite Mr. Pierce's assertion that the bronchodilator marketplace was where the Respondent intended to enter, he could only name one competitor. [FOF 123]. Thus he demonstrated his lack of knowledge concerning the bronchodilator market. [*Id.*].

In total, such speculative conduct is not tantamount to substantial evidence that the Respondent is one who seeks to sell its product as a bronchodilator in the United States. [*See* Alvin Darby, M.D., 75 FR 26,993, 26,999 (DEA 2010) (citing NLRB v. Columbian Enameling & Stamping Co., 306 U.S. 292, 300 (1939) (''under the substantial evidence test, the evidence must do more than create a suspicion of the existence of the fact to be established.'')]. Accordingly, I find the Respondent has failed to establish that its product would be imported to provide for medical, scientific, or other legitimate purpose. Therefore the Respondent failed to carry its burden of proof under 952(a)(1).

b. Necessity

The Respondent has similarly failed to satisfy the second prong of the CSA's standard: that its product is necessary to meet the stated purpose. While the DEA has clarified that the term ''necessary'' is not meant to limit competition in a valid marketplace, the proponent must still establish such need exists. [*See Johnson Matthey,* 67 FR at 39,043]. Again, the Respondent has failed to meet that burden. Even assuming the Respondent had demonstrated that the intended purpose for its product was medical, use as a bronchodilator, it introduced no evidence as to the need

[18] 28 CFR 0.100 and 0.104.

[19] Although later in this decision I find Mr. Pierce's testimony regarding his failure to conduct market research incredible, to clarify, I do find credible his testimony that he failed to conduct such research on the bronchodilator market.

for any ephedrine/guaifenesin combination product in the United States for such use.[20] Indeed, it only speculated that persons would purchase its product for that purpose. [FOF 116, 117, 119, 120, 121, 123]. Similarly, despite the Respondent's recognition that a 12.5 mg ephedrine/400 mg guaifenisen OTC product is not currently available in the United States, it speculated that that product was necessary as an ''extra strength'' formula. [FOF 104, 105]. Such speculation, however, is not substantial evidence of need. [*See Darby,* 75 FR at 26,999].

Accordingly, this case is starkly different from earlier DEA rulemakings under 952(a)(1). In *Johnson Matthey,* 67 FR at 39,041, the Respondent introduced extensive expert testimony as to the need for narcotic raw materials (''NRMs'') in the United States. The expert concluded that NRMs are ''necessary to the United States medical community, as there are medical demands that cannot be met by non-opiate narcotics'' He clarified, ''opiate pharmaceuticals have a long history of medical use and the medical community continues to rely upon opium-derived alkaloids rather than synthetic opiate analgesics. These alkaloids and their semi-synthetic derivatives such as hydromorphone, hydrocodone, and oxycdone are critical therapeutic agents today.'' He concluded, ''that morphine, codeine, hydromorphone, hydrocodone and oxycodone are necessary to the United States medical community.'' [*Id.* at 39,042–3].

Here, the Respondent failed to present such evidence of need for its product. Therefore, based on this record, the DEA cannot similarly conclude that Respondent's import is necessary in the United States.[21]

Accordingly, as the Respondent has failed to prove by a preponderance of the evidence that its importation of an ephedrine/guaifenesin product is necessary for medical, scientific, or other legitimate purposes in the United States, it is my recommendation that the DEA not initiate rulemaking proceedings to permit such importation based on this record.

2. Adjudication

Consistent with 21 U.S.C. 958(c)(2)(A) ''The Attorney General shall register an applicant to import . . . a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest.'' [21 U.S.C. 958(c)(2)(A)]. Likewise, the public interest shall be determined consistent with the provisions in section 823(h). [21 U.S.C. 958(c)(2)(B)]. In making this determination, Congress directed that the Administrator consider the following:

(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.

[21 U.S.C. 823(h)].

''These factors are considered in the disjunctive.'' [Joy's Ideas, 70 FR 33,195, 33,197 (DEA 2005)]. The Administrator may rely on any one or a combination of factors, and may give each factor the weight she deems appropriate in determining whether an application for registration should be denied. [*See e.g.,* David M. Starr, 71 FR 39,367 (DEA 2006); Energy Outlet, 64 FR 14269 (DEA 1999); Morall v. DEA, 412 F.3d. 165, 173–4 (DC Cir. 2005)]. The Administrator bears the burden of proof with regard to this adjudication. [21 C.FR. 1301.44].

a. 4 OTC's maintenance of effective controls against diversion into other than legitimate channels.

In line with DEA precedent, ''this factor encompasses a variety of considerations including, inter alia, the adequacy of physical security, the adequacy of recordkeeping, and whether a registrant is selling excessive quantities of the products.'' [CBS Wholesale Distributors, 74 FR 36,746, 36,749 (DEA 2009)]. In addition, under this factor, the DEA will consider whether the Respondent is serving an illegitimate market based on whether the sale of ephedrine products is inconsistent with the known legitimate market and known end-user demand for products of this type. [*See e.g.* Hilmes Distributing, Inc., 75 FR 49,951 (DEA 2010); Gregg & Sons Distributors, 74 FR 17,517 (DEA 2009)].

(1) Illegitimate Market

The illegitimate market that the Government purports to exist in this case, is distinct from that contemplated in other list I chemical cases. In prior cases, the DEA has expressed its concern about the sale of ephedrine into the ''grey market,'' i.e. to convenience stores and gas stations, as individuals seeking to convert ephedrine into methamphetamine typically seek out these retailers versus their larger national chain competitors. [Joys Ideas, 70 FR 33,195, 33,196 (DEA 2005) (describing the grey versus traditional market); *Gregg & Sons,* 74 FR at 17,523 (clarifying that such distribution is a factor and not a per se rule precluding a respondent's registration)]. The agency's concerns about grey market distribution are best summarized as follows: ''the illegal manufacture and abuse of methamphetamine pose a grave threat to this Nation. . . . Methamphetamine abuse has destroyed numerous lives and families, and has had a devastating impact on many communities. Moreover, because of the toxic nature of the chemicals used in making the drug, illicit methamphetamine laboratories create serious environmental harms.'' [*CBS Wholesale,* 74 FR at 36,747].

Here, the Government argues that the illegitimate market that the Respondent would serve is the market for ephedrine as a dietary supplement. [*See* Govt. Brief at 40 (stating that the Respondent's product is not ''destined for a legitimate market'')] [*Id.* at 44 (stating the Respondents marketing ''implied ephedrine's illicit use'')]. The FDA banned the sale of an ephedrine product as a dietary supplement in 2004, finding that such a product is ''adulterated.'' The FDA prohibits the adulteration of a drug as well as the introduction, delivery, or the receipt of an adulterated product in interstate commerce. 21 U.S.C. 331 (a)–(c). [*See* 69 FR 6,788 (FDA 2003); 21 C.F.R 119.1 (2010)]. The FDA further prohibits the marketing of a bronchodilator as a dietary supplement as such constitutes misbranding. [21 U.S.C. 331(b)]. Consequently, the dietary supplement

[20] Although, I recognize the Respondent's emphasis that the FDA approves marketing products similar to the Respondents' as bronchodilators in the United States, such is not evidence of actual need for that type of product.

[21] However, in the event that the Deputy Administrator wishes to take official notice of DEA publications regarding the importation of ephedrine then those publications may demonstrate some need for ephedrine in the United States for the purpose for which the Respondent proposes its import. [*See* 75 FR 4973, 4973–4 (DEA 2010) (stating ''ephedrine, pseudoephedrine, and phenylpropanolamine are used to produce drug products lawfully marketed under the Federal Food, Drug and Cosmetic Act (FFD&CA), many of which are prescription drugs . . . . These chemicals are also used in over-the-counter (OTC) drug products (lawfully marketed and distributed under the FFD&CA as a non-prescription drug''); 75 FR 79,407 (DEA 2010) (setting forth the established assessment of annual needs for 2011 for ephedrine in the United States)].

market for an ephedrine product remains an illegitimate market.[22]

The Government has provided no evidence of the actual legitimate market for ephedrine as a bronchodilator, other than general information as to market trends. [*See* FOF 9–12]. These generally downward market trends for ephedrine as an asthma medication, however, lend credence to the possibility that the Respondents in fact intend to sell its product as a dietary supplement. Yet, as it is impossible to ascertain whether the Respondent's importation would exceed legitimate demand, I cannot find on this record that the Respondent's product is thus likely to be diverted for such sale or for another illicit purpose, such as the conversion of it into methamphetamine. I am similarly unmoved to find the evidence in this record of market trend analysis weighs in favor of denying the application. [*See Greg & Sons,* 74 FR at 17,520; *CBS Wholesale,* 74 FR at 36,748].

(2) Security Measures

Whether the Respondent has adopted adequate controls against the diversion of its product for illicit use, i.e. its conversion into methamphetamine, in accordance with DEA regulation is also relevant to the ultimate issue of whether its registration is in the public's interest.

In 1995, DEA promulgated 21 C.F.R 1309.71(a), which directed that ''[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of list I chemicals.'' This regulation, which remains in effect, further explained that ''[i]n evaluating the effectiveness of security controls and procedures, the Administrator shall consider:

(1) the type, form, and quantity of list I chemical handled;

(2) the location of the premises and the relationship such location bears on the security needs;

(3) the type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) the availability of electronic detection and alarm systems;

(5) the extent of unsupervised public access to the facility;

(6) the adequacy of supervision over employees having access to List I chemicals;

(7) the procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored; and

(8) the adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.''

[*Id.*].

The Government does not address the Respondent's security measures at its new location. The Government only refers to the Respondent's initial location and its failure to have proper security for the assertion that the Respondent's application has been ''fraught with problems.'' [Govt. Brief at 44].

The Respondent, however, argues that its security exceeds that required by the DEA for the storage of list I chemicals and therefore adequately protects against diversion. [*Id.* at 7–8].

i. Type, Form, and Quantity of Ephedrine

The Respondent intends to handle finished form combination ephedrine. The Respondent's proposed combinations include a 12.5 mg ephedrine/200 mg guaifenesin formula, a 25 mg ephedrine/400 mg guaifenesin formula, and a 12.5 mg ephedrine/400 mg guaifenesin formula. [FOF 104]. Although the Government argues that the Respondent's 12.5/400 mg guaifenesin formula is unprecedented, it does not argue nor has it produced any evidence that the Respondent's product includes an atypical or excessive amount of ephedrine. Accordingly, the Respondent's security measures do not merit a finding that it has inadequate diversion controls under this provision.

ii. Location of the Premises

Next, the Respondent's proposed location is in Phoenix, Arizona. [FOF 33]. The Respondent proposes to store the chemical in a large warehouse where other companies store their products. Due to this location, increased security measures may be required. However, the Respondent's procurement of a locked cage with limited access that is guard monitored during the day and alarm monitored with law enforcement notification at night, addresses these concerns. [FOF 143(a)].

iii. Building

The Respondent's building is secured by an eight foot fence topped with razor wire, as well as surveyed by guards during normal business hours. The Government has provided no evidence that such is inadequate security. [FOF 35].

iv. Availability of Electronic Detention and Alarm Systems

The Respondent's SOPs as well as the security document by Freeport Logistics demonstrate that the Respondent has electronic detection and alarm systems that are active at night and triggered to notify authorities in the event of a break-in. [FOF 35; 143(a)]. Once again, there is no evidence that such inadequately protects against diversion.

v. Extent of Unsupervised Public Access

Although the Respondent's chemicals would be stored in a warehouse where other companies could conceivably have access, the products are not otherwise accessible by the public. In addition, other companies' access to those products is prevented by the Respondent's SOP that those chemicals be stored in a locked cage to which only the Respondent's employees have access. [FOF 142(a)].

vi. Adequacy of Supervision Over Employees Having Access to Ephedrine

Although the Respondent has stated in its SOPs that only designated employees will have access to this cage, the Respondent's definition of employees is unusually broad. [*See* FOF 143(a) n. 16 (defining employees as ''all persons that perform *any* business related activity at the facility *or* regarding the ephedrine chemical drug product'')]. This concern is somewhat exacerbated by the fact that GFR was noted by Health Canada for a similar issue. [*See* FOF 57 (stating ''although only two GFR designated employees have access to raw bulk ephedrine (posses the physical keys), all 61 employees conceivably have access to ephedrine at other stages of the production (blending, bulk, tableting, packaging, as well as shipping)'')]. However, the Respondent will screen those employees by conducting background investigations and drug testing. The Respondent also will only allow designated employees access to the cage. There being no evidence to the contrary, the Respondent's security measures appear adequate under this provision. [FOF 143(a), (b)].

vii. Procedures For Handling Business Guests and Visitors

It is the warehouse's policy that ''all Freeport contractors for hire must show proof of background checks for anyone entering'' the facility. [FOF 35]. While neither the SOPs nor Freeport's security document address the Respondent's handling of other non-employees that enter the premises, the Respondent's policy to disallow non-designated employees access to the ephedrine cage

[22] It is important to note, however, that contrary to the Government's assertion, it is the sale, and not the use, of an ephedrine product as a dietary supplement that makes this market an illegitimate one. [*See* Govt. Brief at 39].

adequately addresses any concerns that may arise under this provision. [*See* FOF 143].

viii. Adequacy Of Systems For Monitoring The Receipt, Distribution And Disposition Of List I Chemicals In Its Operation.

As for the Respondent's measures under this provision, the Respondent's SOPs state that all schedule listed chemical products ''are immediately placed within the storage area upon receipt or returned to the storage area when not being transported.'' [FOF 143(a)(v)]. In addition, the SOPs state ''when temporarily stored in preparation for shipment outside of the caged area within Freeport Logistics, the product will be under constant observation by employees of the company and shipping containers will be unmarked, not indicated [sic] they contain [schedule listed chemicals] to guard against in-transit losses.'' [FOF 143(d)(v)]. Although the Respondent does not address its policy on disposition, the Government does not argue such warrants an adverse finding under this provision.

Therefore, the Government has not introduced any evidence that the Respondent has inadequate security at its current location. In addition, Mr. Mudri credibly testified that the Respondent's security measures are adequate to store controlled substances and thus exceed that required to store list I chemical products. [FOF 34, 35]. Although, as discussed *infra,* while I give less weight to other portions of Mr. Mudri's testimony, based on the remoteness in time of his most recent tenure at DEA, as well as the scope of his work for this agency, I find that his experience renders him more than qualified to testify as to the Respondent's compliance with security regulations that have been in effect, in relevant part, since 1995. [*See* 21 CFR 1309.71 (1995), FOF 34, n.8].

In addition, the relevant inquiry is whether the Respondent's current measures [23] are adequate, so that if it were granted a registration today, such would be consistent with the public's interest. [*See Mr. Checkout,* 75 FR 4,418 (DEA 2010) (finding that where the Government has only met its burden of proof regarding allegations that Respondent violated storage regulations for List I chemicals, and Respondent, after notification of violation, quickly corrected the infraction, the Respondent's registration is consistent with the public interest)].

Therefore, I find that factor I weighs in favor of granting the Respondent's application.

b. 4 OTC's Experience in Handling List I Chemicals and Compliance with Applicable Federal, State, and Local Law.

Under factor two, the agency will consider the Respondent's past compliance with applicable federal, state, and local law as well as the Respondent's experience in handling list I chemicals. It has been this agency's longstanding principle that past performance is the best indicator of future compliance. [*See* Alra Labs v. DEA, 54 F.3d 450, 452 (7th Cir. 1995)]. Therefore, where the Respondent has negative experience in handling list I chemicals, the agency will find this factor weighs in favor of revocation or denial of an application. [ATF Fitness Products, Inc., 72 FR 9,967, 9,968–9 (DEA 2007)]. In addition, where the Respondent has no experience in handling list I chemicals and cannot otherwise demonstrate compliance, the agency has denied the Respondent's registration. [Express Wholesale, 69 FR 62,086, 62,089 (DEA 2004) (lack of experience plus absence of an adequate business plan is significant); *Joys Ideas,* 70 FR at 33,198; (likewise); Matthew D. Graham, 67 FR 10,229, 10,230 (DEA 2002)].

(1) Respondent's Compliance With DEA Law.

i. Past Experience of Richard Pierce and Kevin McIsaac in Handling Ephedrine

Here, the Respondent is a new company and therefore has no experience in importing, handling, or distributing list I chemicals in the United States. [FOF 25]. Two of the Respondents owners, Kevin McIsaac and Richard Pierce, however, have held Canadian Class A Precursor Licenses. [FOF 39, 40, 47, 49, 96, 98]. The DEA has previously held that actions of a company's owners must be imputed to the company itself. [*See e.g.* Jacqueline Lee Pierson Energy Outlet, 64 FR 14,269, 14,271 (DEA 1999) (stating ''DEA has consistently held that a retail store operates under the controls of its owners, stockholders, or other employees, and therefore the conduct of these individuals is relevant in evaluating the fitness of an applicant for registration.'']. Therefore, to the extent that Canada's regulation of list I chemicals mirror the DEA's requirements, these individuals' track record of compliance with Canadian law is helpful in determining whether the Respondent could or would similarly comply with DEA law. [*See* FOF 23].

The Government has proven several violations of Canadian law by Kevin McIsaac. Specifically, McIsaac failed to lock the drawer that contained the key to the Class A precursor cage, failed to keep an ephedrine movement log, and failed to record cage ephedrine movements and the full name of person(s) accessing the cage. In addition, the agency found several ''suspicious transactions'' that McIsaac failed to record. [FOF 42]. The Government has provided circumstantial evidence [24] that those violations formed a basis for McIsaac's surrendering of its precursor license to Health Canada in 2008. [FOF 43]. The Government also produced evidence that McIsaac shipped ephedrine to addresses that could not be confirmed. [FOF 44]. However, while 4 Ever Fit's customer list included companies with U.S. addresses while Mr. McIsaac owned that product, the Government failed to prove that the 4 Ever Fit product was actually purchased by those U.S. customers during his ownership. [FOF 45, 46].

Although the Respondent argues that ''these transactions . . . were made before Richard Pierce acquired the brand name 4 Ever Fit in 2008'' that fact is entirely irrelevant to this inquiry. [Resp. Brief at 8]. There is no dispute that Kevin McIsaac has a current ownership interest in the Respondent.[25] Therefore, by entrusting the Respondent with a DEA registration, so would Kevin McIsaac be entrusted. Accordingly, Kevin McIsaac's history of non-compliance with Canadian law, and the significance of that non-compliance given his decision to then relinquish his Class A license, negatively impacts a finding that he could ensure the Respondent's compliance with DEA law.

Next, the Government introduced evidence that GFR violated Canada's precursor regulations. [*See* FOF 55]. Specifically, the Government introduced Health Canada's inspection report of the Respondent, which stated ''GFR does not maintain a precursor access log. No record exists tracking personnel accessing stock either within the precursor cage, or within the overall warehouse.'' [FOF 57].

[23] Although the Government assessed the Respondent's prior location, [FOF 28–32], I find that assessment nonpersuasive given the additional facts pertaining to the Respondent's current location and its SOPs regarding security issues.

[24] The Respondent asserts that Mr. McIsaac surrendered his precursor license because his company no longer needed the registration. Mr. Pierce already had such a registration. Yet I do note the violations as being relevant here.

[25] The actual percentage ownership interest that Mr. McIsaac has in 4OTC, however, is unclear. [*See* FOF 98].

The Respondent, however, argues that ''conduct amounts to activity that is legal within Canada'' and those were mere ''observations'' and not ''citations'' in Health Canada's report. [Resp. Brief at 9–10]. Not only is this argument unpersuasive, it is untrue. Canadian law clearly states ''[a] licensed dealer shall keep, at the licensed site, a record showing, for each day on which a person has access to a place at the site where a Class A precursor is kept, the person's name and the date of access.'' [Canada Department of Justice, Precursor Control Regulations, Sec. 85(3) (2010)]. Therefore, in failing to maintain such an access log, GFR violated Canadian law. In addition, the Government established that GFR had a shortage of 79,000 tablets of ephedrine, and the Respondent does not address corrective measures proposed to prevent this type of shortage in the future. [FOF 56; *See gen.* Resp. Brief].

Nevertheless, I do find it significant that despite this regulatory infraction and shortages, and after numerous inspections by Health Canada, GFR Pharma has maintained a precursor license in Canada. [FOF 58–60]. Indeed, the record reflects that GFR handles a significant amount of ephedrine and its business practices reflect that it has relevant experience in handling ephedrine in Canada and could similarly handle ephedrine in the United States, where the DEA's laws are similar. [*See* FOF 49–52].

The Government further introduced evidence of a custom's seizure of GFR's product to suggest that the Respondent's past experience in handling ephedrine weighed in favor of denying its registration. [FOF 61–73]. However, the illegal aspects of that shipment cannot be attributed to the Respondent; therefore, the Government's argument on this basis fails. While Better Bodies attempted import violated both Canadian and U.S. law,[26] and One Stop Nutrition's failure to self certify violated DEA law,[27] the Government has failed to prove that Mr. Pierce was aware that Better Bodies would attempt to ship its product into the United States or in any way encouraged or facilitated that shipment other than selling its product in accordance with normal business practices. [FOF 73]. Therefore, under these circumstances, the fact that Better Bodies purchased GFR's product and attempted to ship it illegally does not weigh in favor of denying this Respondent's registration.[28]

ii. Respondent's Lack of Experience in Complying with DEA's Laws

As there are some aspects of DEA law that are unique, the Respondent's lack of experience in complying with such law will weigh against its registration, unless it can otherwise demonstrate it is capable of compliance. [*See Express Wholesale,* 69 FR at 62,089; *Joy's Ideas,* 70 FR at 33,198].

Here, the Respondent introduced its Standard Operating Procedures into evidence to demonstrate it is capable of complying with DEA law. [FOF 143]. Therein, the Respondent addressed the DEA's sales and recordkeeping requirements, shipping policies, importation requirements, and employee hiring mandates. [FOF 143]. The Respondent introduced testimony by its consultant that these policies were ''a good start with regard to operations.'' [FOF 147]. However, I give less weight to Mr. Mudri's testimony regarding the Respondent's compliance with these laws, as opposed to the security laws discussed *supra,* as he has not acted for the DEA in over 10 years, and the law has developed since his departure. [FOF 34, n.8, FOF 147, n. 17]. Indeed, he was unaware of the DEA's new requirement that retail sellers of ephedrine via the internet must self-certify with the DEA. [FOF 148]. Nevertheless, the Government has introduced no evidence nor made any argument that the Respondent's SOPs inadequately address the DEA's requirements,[29] therefore, I do not find that its lack of experience in complying with DEA law weighs in favor of denying its registration under factors II and IV.

Accordingly, in total I do not find the Respondent's experience in handling ephedrine weighs against its registration. While I am troubled by Mr. McIsaac's violations of Canada's regulations as I find those to be more significant than GFR's, I am persuaded by the fact that Mr. Schiefelbein will oversee the day-to-day operations of the company and that Mr. McIsaac will have no participation in that operation. [FOF 97, 98]. Furthermore, while I take notice of GFR's Canadian regulatory infractions, Mr. Pierce otherwise has a good track record of compliance with Health Canada's laws. [FOF 58–60]. Therefore, this experience lends credence to the fact that he would similarly comply with the DEA's laws. [See *Gregg & Sons,* 74 FR at 17, 524 (finding that despite infractions, the Respondent's overall record of compliance indicated he could be entrusted with a DEA registration)]. In addition, the Respondent's lack of experience in complying with DEA law is mitigated by the adequacy with which its SOPs address these laws, and the Government's failure to challenge them.

(2) Compliance with FDA law

The Controlled Substances Act makes clear that the DEA is to consider the Respondent's compliance with all applicable federal law in ascertaining whether to grant it a DEA registration. [21 U.S.C. 823(h)(2); *See also* ATF Fitness, 72 FR 9,967, 9,969 (DEA 2007) (stating ''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'')]. Indeed, where the Respondent has violated FDA law, the DEA has denied it a registration. [*See ATF Fitness,* 72 FR at 9,969 (where the FDA inspected the Respondent and found (1) it had in its possession products that were banned in 2004; (2) it had failed to comply with the FDA's recordkeeping requirements; and (3) it had possessed mislabeled products)]. Therefore, if the Respondent's proposed practice will violate FDA law, the Respondent's application could be denied.

However, in a recent decision, the Administrator emphasized that she is without authority to definitively interpret the Food Drug and Cosmetic Act, and will not do so. [Tony T. Bui, M.D., 75 FR 49,799, 49,989 (DEA 2010)]. The Administrator then applied this ruling in *Paul Weir Battershell, N.P.,* Doc. No. 09–51 (July 15, 2011) (unpublished). There, she refused to find a violation of FDA law by a nurse-practitioner's prescription of Human Growth Hormone (''HGH'') on the basis that ''whether Congress intended to criminalize all prescribing of HGH by non-physicians, including those who can lawfully prescribe under state law, is quintessentially one for judicial cognizance.'' [*Id.* at 33, n.27]. However, she also found that ''Respondent's plea agreement does . . . establish that he violated the FDCA by causing the introduction of a misbranded drug into interstate commerce.'' [*Id.*].

Accordingly, two principles emerge from the Administrator's rulings. First, if the Government presents evidence of

[26] Canada has exportation requirements similar to the DEA's and the DEA requires an entity to register with the DEA prior to importing a list I chemical into its territory. [*See* Health Canada, Precursor Control Regulations 6, 7, 69 (2010) (requiring an exporter of precursor chemicals to register with Health Canada; 21 U.S.C. 957(a) (2006) (requiring an importer of precursor chemicals to register with DEA); FOF 17].

[27] FOF 16, 70.

[28] However, as discussed further under Factor V, Mr. Pierce's reaction to that shipment does weigh against the Respondent's registration.

[29] [*See gen.* Govt. Brief].

conduct by the Respondent that is plainly inconsistent with FDA law, then it has met its burden of proof as to the Respondent's noncompliance. Similarly, if the Government establishes a violation through plea agreement, or other irrefutable evidence, such will also weigh negatively against its registration, specifically, a finding of the Respondent's ability to comply with the CSA. [*See id.; ATF Fitness,* 72 FR at 9,969]. If, however, the Government presents evidence of conduct that *may* be a violation of FDA law, yet would require the agency to render an interpretation of the FDCA to reach such a violation, then such exercise is beyond the jurisdiction of the DEA and will have no bearing on the Respondent's registration under Factor II.[30]

i. FDA Labeling and Misbranding Provisions

Here, the Government has established a clear violation by the Respondent of the FDA's misbranding provisions.

The Food and Drug Administration regulates over-the-counter medications by setting forth approved over the counter combinations and guidelines for labeling those products in an OTC Monograph. [*See* Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use, Final Monograph, 51 FR 35326 (1986) (codified at 21 CFR part 341)]. If a product's label lacks required information or contains false or misleading information, the FDA deems that product misbranded. [21 U.S.C. 352(a),(c); FDA, Key Legal Concepts: ''Interstate Commerce,'' ''Adulterated,'' ''Misbranded'' 1 (Feb. 9, 2006) (stating ''under the FD&C the term 'misbranding' applies to . . . [f]alse or misleading information . . . [and l]ack of required information . . . .'')]. The FDA prohibits the introduction of a misbranded product into interstate commerce. [21 U.S.C. 331(b)].

The FDA Monograph requires an OTC bronchodilator[31] label to contain the following statement under the heading ''indications:'' ''For temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.'' [21 CFR 341.76(b), (b)(1). The FDA emphasizes that including this language is not discretionary. [*Compare* 21 CFR 341.76(b)(1) with (b)(2).]. The Respondent's proposed packages do not contain the required language. [*See* FOF 127]. Therefore, as the Respondent's proposed packaging plainly violates the FDCA, such weighs in favor of denying its registration.[32]

In addition to requiring certain labeling, the FDA permits OTC bronchodilators to list other indications, as provided in § 371.76(b), as well as other truthful and nonmisleading statements describing those indications. [21 CFR 341.76(b)]. None of those indications include using the bronchodilator for weight loss or otherwise as a dietary supplement. [341.76(b)(2)]. In addition, the definition of ''label'' in the context of misbranding has been construed broadly by federal courts to include a circular, pamphlet, brochure, newsletter, or other piece of literature that helps sell a product, even if it did not accompany the drug when traveling across state lines. [*See* V.E. Irons, Inc. v. United States, 244 F. 2d 34 (1st Cir. 1957); United States v. 47 Bottles, More or Less, Jenasol Rj Formula 60, 320 F.2d 564 (3d Cir. 1963)].

Here, the Respondent's packaging originally contained a logo naming the product ''4 Ever Fit.'' Although this label raises concerns under the FDA's proscription against nonmisleading statements on the products packaging, the Respondent's current label, which lacks that logo, does not. [*See* FOF 112, 127]. Therefore, I find whether, under these circumstances, there would have been a violation of this regulation is moot in light of the Respondent's new measures.

In addition, whether the Respondent's internet sale of its product further violates the FDCA's misbranding provisions, depends entirely on how it intends to market its product. Despite numerous assertions to the contrary, there is substantial evidence that the Respondent would market its product similar to its stated competitor, Vasapro. [*See* FOF 143(d)(i) (assertion of compliance with FDA law); FOF 102, 111, 124 (asserting the product will only be sold as a bronchodilator and will be sold separate from 4EF USA's products); FOF 91 (asserting its only competitor is Vasapro)]. The marketing of Vasapro's product raises serious misbranding concerns. [FOF 92 (marketing of Vasapro as weight loss and dietary supplement)]. Nevertheless, whether the FDA would deem such statements misleading and, accordingly, such marketing misbranding is an issue beyond the ken of this tribunal, and therefore will not weigh in favor of nor against the Respondent's registration.

In light of the foregoing, I find that the Respondent's practice will plainly violate the FDCA's required labeling for indications by not stating that the product is ''for temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.'' However, I do not find, *in toto,* that the Respondent's level of compliance with FDA law indicates that the Respondent is either unwilling or unable to comply with the CSA.

[30] Here, although the Government urges throughout its brief that the Respondent's practice would violate FDA law, the Government has failed to point out *any* specific provision of FDA law that the Respondent's proposed practice would violate. [(*See* Govt. Brief)].

[31] The FDA's monograph on OTC medications currently approves the use of ephedrine as a primary ingredient in OTC bronchodilators. [21 CFR 341.16]. Although in 1995, the agency promulgated a proposed rule to remove ephedrine from the monograph, the agency has not taken final action on that rule. [*See* 60 FR 38,643]. Similarly, although the FDA issued a proposed rule in 2005, eliminating combination ephedrine/guaifenesin from the OTC Monograph, due to its determination of the limited clinical effectiveness of guaifenesin in the treatment of asthma, the FDA has yet to issue a final ruling on that regulation. [*See* 70 FR 40,232 (2005)]. Therefore, under the FDA's current monograph, the Respondent's product may be sold over the counter as bronchodilator medications. [*See* FOF 104; 21 CFR 341.18 (listing guaifenesin as the expectorant active ingredient included in the cough-cold monograph)].

[32] The FDA Monograph requires OTC bronchodilators to have a ''statement of identity.'' Accordingly, the Monograph requires the label to contain ''the established name of the drug, if any, and identifies the product as a ''bronchodilator.'' [21 U.S.C. 341.76]. Here, the Respondent's label contains the word ''bronchodilator,'' albeit inconspicuously, under the term ''Purpose'' and under the section labeled ''Drug Facts.'' [FOF 127(b)(1)]. However as this language is not plainly inconsistent with FDA's regulation, I do not find the Respondent's proposed ''statement of identity'' weighs in favor of denying its registration.

The OTC Monograph further requires bronchodilator products be labeled with the following warnings and directions for use:

(1) ''Do not use this product unless a diagnosis of asthma has been made by a doctor.''

(2) ''Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.''

(3) ''Do not use this product if you have ever been hospitalized for asthma or if you are taking any prescription drug for asthma unless directed by a doctor.''

(4) *Drug interaction precaution.* ''Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.''

(i) ''Do not continue to use this product, but seek medical assistance immediately if symptoms are not relieved within 1 hour or become worse.''

(ii) ''Some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your doctor.''

(iii)''Adults and children 12 years of age and over: Oral dosage is 12.5 to 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Do not exceed recommended dose unless directed by a doctor. Children under 12 years of age: Consult a doctor.''

[21 CFR 341.76]. The Respondent's proposed packaging label contains that language verbatim. [*See* FOF 127].

(3) State Law

Similar to the FDA's laws, the Respondent has no experience in complying with the complex state regulatory and statutory schemes that apply to ephedrine. [FOF 125; *See* FOF 129]. Some states have scheduled ephedrine as a controlled substance, therefore prohibiting the Respondent from selling its product in that state. [*Id.*]. Other states require licensure. [*Id.*].

Although the Respondent has assured this tribunal throughout its DEA application, the hearing, and in its post-hearing brief that it intends to comply with all laws governing its practice,[33] the Respondent has also demonstrate a general unfamiliarity with state laws. For example, the Respondent failed to recognize the need for a non-drug wholesale permit in Arizona, the state where it intends to store ephedrine, prior to the hearing in this matter, when the Government's counsel highlighted the need for it on cross-examination. [FOF 137, 138].

In addition, deficiencies in its SOPs fail to provide further assurance that it is capable of compliance with state law. For example, the SOPs' requirements for the State of Michigan indicate that a state license is required; they list the maximum number of packages that may be sold per transaction as 2; state the maximum number of grams of the 4 OTC product that can be sold per month as 9 and cannot exceed a 25/400 ephedrine/guaifenesin combination; indicate the Respondent must keep records for 6 months; and further provide the minimum age for purchase is 18, and both photo ID and signature are required. However, the SOPs completely overlook the fact that the state of Michigan expressly prohibits the internet sale of ephedrine into its territory. [FOF 134]. Therefore, if the Respondent was to rely on its SOPs and sell its products through the internet to customers in Michigan, it would violate state law.

In addition, under the bulleted outline for New Hampshire, the SOPs only state ''comply with federal regulations.'' When Mr. Pierce was questioned about this SOP he agreed that he could be pretty certain that New Hampshire would allow 4 OTC to sell ephedrine into the state, so long as they were compliant with federal regulations. [FOF 132]. Later in the SOPs, however, on the chart for state requirements, there is a ''Y'' under the column marked ''state license'' corresponding to the state of New Hampshire. [FOF 132]. While the Government has not provided evidence of whether in fact New Hampshire does require such licensure, this internal inconsistency raises compliance concerns if this document were to be relied on by the Respondent. Furthermore, the Respondent's expert, Mr. Mudri, was unfamiliar with state law and therefore could not ensure the Respondent's compliance. [FOF 139].

The inadequacies of the Respondents SOPs on state law underscore my concerns with its registration. Although the Respondent argues that it has completed its due diligence in investigating their legal obligations, they also state that their SOPs are a ''work in progress'' and that they are relying on their counsel to bring them further into compliance. [FOF 135–36]. However, as the Respondent points out, its application has been pending before this agency since 2007. [FOF 26]. Despite that amount of time, the Respondent has yet to ascertain how to conduct its internet business within the confines of state law. Therefore, I am not persuaded that it would be able to do so in the immediate future, and I find accordingly that its lack of experience, and failure to otherwise demonstrate compliance with state law, weighs against its registration.

c. Respondent's Prior Conviction Record Under Federal or State Laws Relating To Controlled Substances Or To Chemicals Controlled Under Federal or State Law;

Neither the Respondent, nor its owners have been convicted of an offense related to controlled substances or list I chemicals, therefore, this factor weighs neither in favor nor against granting the Respondent's registration. [*See* Dewey C. Mackay, M.D., 75 FR 49,956, 49,973 (DEA 2010) (stating ''while a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry'') (citing Jayam Krishna-Iyer, 74 Fed Reg. 459, 461 (DEA 2009); Edmund Chein, M.D., 72 FR 6,580, 6,593 n.22 (DEA 2007)].

d. Other Factors Affecting the Public's Interest

The DEA will consider factors I through IV as well as other factors that affect the public interest to determine whether the Respondent's registration is consistent with the public interest. The agency has clarified the bounds of the considerations it makes under Factor V, however, in stating it is limited ''to those where there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' [*Bui,* 75 FR at 49,988; *See also ATF Fitness,* 72 FR at 9,967].

Here, the Government does not allege that the Respondent's registration will be used as a conduit for the diversion of ephedrine into the clandestine manufacture of methamphetamine. Indeed, the threat of diversion created by the Respondent's registration is the internet sale of its products. However, the DEA does not outlaw the sale of ephedrine via the internet and has instead promulgated regulations setting daily and monthly sales limits and requiring records of all sales to address this issue. [*See* 21 U.S.C. 1310, et seq. and 1314.100 et seq.]. Therefore, the Respondent's internet sales alone do not weigh in favor of denial of its registration under this factor.

The Government argues, however, that the Respondent's registration is inconsistent with the public interest, due to its failure to disclose a list of customers at the time of registration. During the hearing Ms. Klett testified on behalf of the DEA that the agency requires a customer list along with an importer registration because the Department of Justice urged the DEA to implement new protocols to better regulate precursors to methamphetamine production. [FOF 18]. Therefore, once the DEA receives the customer list, it verifies each customer to ensure that the importer's product will not be diverted. [FOF 19, 20]. That directive is not in the CMEA, however, nor has the DEA promulgated that requirement into regulation. [*See* 21 U.S.C. 971 (requiring an importer to disclose to whom the list I chemical will be transferred upon import (not application)) and 21 CFR Part 1313)]. Also, the DEA has no such requirement for domestic mail order sales, inferably because the DEA regulates those sales by imposing daily and monthly sales limits to protect against diversion. [*See* FOF 13–15; 21 CFR 1314.01–13.14.155 (2011)].

Here, however, the DEA's policies behind requiring a customer list are satisfied by the Respondent acting as both an importer *and* a retailer; therefore, the Government's argument for denial of the Respondent's application on this basis fails. Here, unlike most other importers, the Respondent does not intend to sell its product to companies who will then distribute it to end users. Instead the

[33] FOF 97, 150; Respt. Brief at 11 (stating ''4 OTC has expended a great amount of time and resources in ensuring that its intended activities relating to the import and distribution of ephedrine containing products within the United States will be in compliance with all pertinent federal and state laws'').

Respondent intends to both import and distribute its product to end users. [FOF 22, 24]. In that regard, the Respondent has already provided the DEA with a customer list of its retail distributors, as it has only one: itself. In addition, not only has the DEA verified that customer, it has specifically investigated that customer to ensure that it has protocols in place to protect against diversion. [FOF 28, 29, 34]. Accordingly, both the purpose behind the CMEA and DEA's policy are met by the disclosure that the Respondent has made in this case, and the Respondent's failure to disclose its retail customers does not otherwise weigh against its registration. [*See* FOF 3 (describing purpose behind CMEA); FOF 19 (describing purpose behind requiring customer list)].[34]

However, under this factor, I find Mr. Pierce's reaction to the Better Bodies shipment into the United States, and his general credibility weigh in favor of denial. When asked whether he still conducted business with Better Bodies after the customs seizure, he stated, ''[w]e have no control over them buying the product from us and shipping it without our knowledge. [Health Canada] . . . has been informed.'' [FOF 73]. However, GFR *does* have control over to whom it sells its product, and GFR's decision to continue to supply a company that has illegally handled its product reflects a general apathy towards diversion. As Mr. Pierce is the President and CEO of GFR, and the principle owner of the Respondent, this factor raises a concern that he would similarly turn a blind eye to the misuse of the Respondent's product in the United States.

Furthermore, Mr. Pierce's testimony throughout this proceeding raises credibility concerns and consequently concerns about whether he could be trusted with a DEA registration. Specifically, during the hearing Mr. Pierce testified that he conducted no market research on the Respondent prior to investing in it, yet was certain that there was a need for its product in the United States as a bronchodilator and that individuals would purchase it over the internet for that purpose. [FOF 116–122]. I find the assertion that he invested in the Respondent blindly, in light of his extensive business experience at GFR and other companies, highly unlikely. [*See* FOF 47, 77, 81, 87]. In addition, I find it more likely that he was aware of the market for ephedrine as a dietary supplement in the United States based on Mr. Schiefelbein's experience selling it as such prior to the FDA's ban in 2004, as well as his own experience selling it for that purpose in Canada. [FOF 83, 53, 54]. Such knowledge likely motivated his investment, a fact he made efforts to conceal during this proceeding. Such lack of candor weighs against the Respondent's registration. [Net Wholesale, 70 FR 24,626, 24,627 (DEA 2005)].

V. Conclusion and Recommendation

In light of the foregoing, I find that the Government has proved by a preponderance of the evidence that the Respondent's registration would be inconsistent with the public interest due to its current inability to comply with state and FDA law, its lack of candor, and its attitude towards diversion. Once the Government has met its burden of proof, the burden shifts to the Respondent to establish that its Registration would otherwise be consistent with the public interest.

Here, the Respondent argues that its registration is consistent with the public interest because, among other reasons, it has completed its due diligence to ensure compliance with all applicable laws and regulations. [*See* Resp. Brief at 10 (stating ''4 OTC has expended a great amount of time and resources in ensuring that its intended activities relating to the import and distribution of ephedrine containing products within the United States will be in compliance with all pertinent federal and state laws'')]. However, it is clear that the Respondent has yet to grasp those laws, because its stated practices stand contrary to them, and its SOPs otherwise fail to adequately address them.

Accordingly, it is my recommendation that the Respondent's application be denied.

Dated: September 22, 2011

/s/Gail A. Randall

Administrative Law Judge

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[34] However, to ensure that the Respondent doesn't evade the customer list disclosure laws by acting as both a retailer and a distributor, I would recommend that if the Respondent's registration is granted, it should be limited to importation and retail sales *only* and the Respondent should be precluded from selling its product to other distributors without first coordinating such registration modification with the DEA. [FOF 117, 118].

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–13]

Donald Brooks Reece II, M.D.; Dismissal of Proceeding

On November 19, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Donald Brooks Reece II, M.D. (Respondent), of Morehead City, N.C. The Order proposed the revocation of Respondent's DEA Certificate of Registration as a practitioner, and the denial of any pending application to renew or modify the registration, on the ground that Respondent's registration is inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f). Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)).

Respondent requested a hearing on the allegations and an Administrative Law Judge (ALJ) conducted a hearing on May 9–13, 2011. Thereafter, on September 30, 2011, the ALJ issued his decision, which concluded that ''Respondent's continued registration would be fully inconsistent with the public interest,'' and recommended that his registration be revoked and that any pending application to renew or modify his registration be denied. ALJ at 33. Respondent filed Exceptions, and on November 21, 2011, the ALJ forwarded the record to this Office for final agency action.[1]

Upon review of the record, it was noted that Respondent's registration was due to expire on April 30, 2012. GX 1. Because in the absence of a timely renewal application, Respondent's registration would expire, *see* 5 U.S.C. 558(c), pursuant to 5 U.S.C. 556(e) and 21 CFR 1316.59(e), I have taken official notice of Respondent's registration record with the Agency.[2] According to

[1] On February 9, 2012, the Government also filed a pleading entitled: ''Notice To The Administrator Regarding State Authority,'' with attachments. Therein, the Government observed that Respondent had entered into a Consent Order with the North Carolina Medical Board, pursuant to which he agreed to cease the practice of medicine or surgery in North Carolina, the State in which he held his DEA registration. Notice to the Administrator Regarding State Authority, at 3. This Order was effective on December 8, 2011. *Id.,* Attachment 5, at 6.

[2] In accordance with the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding-even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To