Decree Library at the address given above.

Maureen M. Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–19657 Filed 8–2–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Green Seal, Inc.

Notice is hereby given that, on June 28, 2011, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Green Seal, Inc. (''Green Seal'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Green Seal has issued a new standard for personal care and cosmetic products.

On January 26, 2011, Green Seal filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 7, 2011 (76 FR 12370).

Patricia A. Brink,

Director of Civil Enforcement Antitrust Division.

[FR Doc. 2011–19443 Filed 8–2–11; 8:45 am]

BILLING CODE 4410–41–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07–43]

Terese, Inc., D/B/A Peach Orchard Drugs; Admonition of Registrant

On July 25, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Terese, Inc., d/b/a/Peach Orchard Drugs (Respondent), of Augusta, Georgia. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes it to dispense controlled substances as a retail pharmacy, and the denial of any pending applications to renew or modify its registration, on the ground that its ''continued registration is inconsistent with the public interest.'' ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Order specifically alleged that Ms. Terese Fordham, the president of Terese, Inc., had applied for and received a DEA Certificate of Registration as a retail pharmacy. *Id.* The Order alleged that Ms. Fordham was married to John Duncan Fordham, who was the pharmacist-in-charge and owner of Duncan Drugs, which had been located at the same address as Respondent. *Id.* The Order further alleged that on May 5, 2005, both Mr. Fordham and Duncan Drugs were convicted of violating 18 U.S.C. 1347, and that on May 25, 2005, Mr. Fordham was ''excluded from the Medicaid program.'' *Id.* The Order then alleged that Mr. Fordham ''violated his conditions of release by unlawfully dispensing Medicaid controlled substances prescriptions by use of another provider's identification number,'' that Fordham was sentenced to 52 months imprisonment, and that Duncan Drugs ''was forfeited to the United States.'' *Id.*

Next, the Show Cause Order alleged that Ms. Fordham had falsified Respondent's application to enroll in Medicaid, and that on December 2, 2006, the Georgia Department of Community Health had denied Respondent's Medicaid application. *Id.* at 2. The Order then alleged that at a state hearing, ''Ms. Fordham and [Respondent's] pharmacist-in-charge declined to present evidence of corporate ownership information to the State.'' *Id.*

Finally, the Show Cause Order alleged that ''DEA considers *for purposes of the Controlled Substances Act* that a retail pharmacy only operates through its officers and agents'' and that ''[t]he registration of a pharmacy may be revoked as the result of the unlawful activity of its owners, majority shareholder, officer, managing pharmacist or other key employee.'' *Id.* (emphasis added). The Order then concluded by alleging that ''[i]n this matter, the restoration of the pharmacy operations to the spouse of the prior owner/operator is not a bona fide transaction but more of a device to retain a DEA registration with no change of control or financial interest by the previous owner who had engaged in misconduct as a registrant.'' *Id.*

Respondent timely requested a hearing on the allegations, ALJ Ex. 2, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). Thereafter, on April 15, 2008, an ALJ conducted a hearing in Charleston, South Carolina, at which both parties called witnesses to testify and introduced documentary evidence. ALJ at 2.

On May 13, 2009, the ALJ issued her recommended decision. Therein, the ALJ rejected the Government's principal theories that Respondent is the alter ego of Duncan Drugs and that the creation of the pharmacy is a sham transaction which was carried out to avoid the consequences of Duncan Drugs' loss of its registration. ALJ at 20–22. While the ALJ also found that Respondent had committed three recordkeeping violations (it failed to note the date of receipt of controlled-substance orders on DEA Form 222, had failed to record an initial inventory, and had not executed a power of attorney authorizing an employee to order Schedule II controlled substances), she found Respondent's attempt to remedy the violations to be ''sincere'' and that the violations ''would not, standing alone, justify revoking its registration.'' *Id.* at 22–24 (citing 21 CFR 1305.13(e), 1304.11(b), 1305.04, and 1305.05(a)). The ALJ also noted that there was ''no evidence that there has been any diversion of controlled substances from Respondent.'' *Id.* at 22. The ALJ thus recommended that Respondent's registration ''be continued, subject to the condition that Mr. Fordham shall have no involvement with Respondent in any capacity, including ownership, management, or as an employee, and shall exercise no influence or control, direct or indirect, over the operation of Respondent.'' *Id.* at 27.

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to my office for final agency action.

During the initial course of my review, I noted that the record indicated that two proceedings were then pending which appeared to be material to the allegations: the divorce proceeding filed by Ms. Fordham and Respondent's appeal of the State's denial of its application to enroll in Medicaid. Accordingly, I ordered that Respondent address the status of these proceedings.

In responding to my order, Respondent noted that Mrs. and Mr. Fordham had voluntarily dismissed without prejudice their claims in the divorce proceeding. Respondent further noted that the Georgia Department of Community Health was now appealing the order of the Superior Court of Richmond County which vacated the Department's Decision.

Having considered the record as a whole, I agree with the ALJ's conclusion that the three recordkeeping violations

are not sufficient to justify revoking Respondent's registration. As for the Government's contention that Respondent's registration may be revoked ''on public interest grounds'' because Duncan Drugs and Duncan Fordham were convicted of health care fraud in violation of 18 U.S.C. 1347 and Respondent's application to participate in Medicaid was denied by the State of Georgia, Gov. Br. at 9 (citing 21 U.S.C. 824(a)(4)), based on section 824's text, structure, and history, I conclude that the Agency's authority under section 824(a)(4) does not encompass these circumstances. Because there is no evidence in this record that Duncan Drugs or Duncan Fordham diverted controlled substances or otherwise violated either the Controlled Substances Act or DEA regulations, I also conclude that the Government's alter ego theory does not apply. I make the following the findings.

Findings

Respondent is a Georgia corporation which operates a retail pharmacy at 2529 Peach Orchard Road, Augusta, Georgia. GXs 3 & 5. Respondent's President is Terese Fordham; Ms. Fordham also owns the vast majority of the Respondent's shares. GX 5, at 2; Tr. 34–35, 37, 110.

In June 2002, Ms. Fordham married John Duncan Fordham. Tr. 115. Mr. Fordham was previously a licensed pharmacist who owned and operated Duncan Drugs, a pharmacy which was located at the same address. Tr. 21; GXs 13 & 14.

On May 25, 2004, both John Duncan Fordham and Fordham, Inc., the corporation which operated Duncan Drugs, were indicted by a Federal grand jury which charged Fordham and his corporation (along with others) with having committed health care fraud in violation of 18 U.S.C. § 1347. GX 16. On May 5, 2005, both John Duncan Fordham and Fordham, Inc., were convicted of the charge. GXs 13 & 16. Thereafter, on May 25, 2005, the Georgia Department of Community Health [hereinafter, DCH] terminated Duncan Drugs' enrollment as a Medicaid provider. GX 13.

On September 15, 2005, the District Court sentenced Fordham to 52 months imprisonment to be followed by three years of supervised release; the Court also imposed several ''special conditions of supervision'' to include, *inter alia,* that Fordham surrender ''any license issued by any state or Federal authority to dispense drugs or pharmaceuticals'' which were ''hereby revoked,'' and that ''he is not to be employed with or without compensation in any pharmacy.'' GX 15, at 1–5.[1] Moreover, on the same day, the Court sentenced Fordham, Inc., to five years of probation. GX 14, at 2. On September 23, 2005, both judgments were entered.[2]

Several months later, Duncan Fordham commenced serving his sentence. In the meantime, Ms. Fordham had contacted David Scharff, a licensed pharmacist, who had been the Director of Pharmacy at Georgia Regional Hospital for more than thirty years. Tr. 72. Ms. Fordham told Mr. Scharff that she intended to reopen the pharmacy to support herself and asked if he would become the pharmacist in charge. *Id.* at 73. Mr. Scharff met with the Fordhams and discussed various issues related to reopening the pharmacy; Scharff agreed to become Respondent's pharmacist-in-charge. *Id.* at 74.

Thereafter, on November 3, 2005, Ms. Fordham submitted an application on Respondent's behalf for a DEA registration as a retail pharmacy. GX 2. Moreover, on November 16, Ms. Fordham filed Respondent's application for a pharmacy license with the Georgia State Board of Pharmacy. GX 5, at 1–3. On January 31, 2006, the State issued a retail pharmacy license to Respondent, GX 10, and on February 10, 2006, DEA issued a registration to Respondent.[3] GX 2, at 1.

On February 13, 2006, Respondent submitted an application to the DCH, which was completed and signed by Mr. Scharff, to become an enrolled Medicaid provider. GX 6, at 5. On the application, Respondent was required to answer a series of questions regarding whether it, or various persons associated with it, had been excluded or sanctioned by either a Federal or State health care program. *Id.* at 4. Respondent answered ''no'' to all of the questions including the third one, which asked: ''Has any family or household member(s) of the applicant who has ownership or control interest in the applicant ever been convicted * * * for any health related crimes or misconduct, or excluded from any Federal or State health care program due to fraud, obstruction of an investigation, a controlled substance violation or any other crime or misconduct?'' *Id.*[4]

Based on this answer, on July 31, 2006, the DCH denied Respondent's application on the grounds that its answer to question 3 was a false representation of a material fact and that Respondent ''is functionally the alter ego of Duncan Drugs which has previously been excluded from the Medicaid program.'' GX 7, at 1. Respondent appealed and a hearing was held before a DCH Hearing Officer.

On December 22, 2006, the Hearing Officer issued his decision. Therein, the Hearing Officer found that Respondent's answer to question 3 was ''an untruthful statement and a false representation of a material fact'' because Respondent had failed to disclose Duncan Fordham's conviction. GX 8, at 10. He also found that Respondent had failed to respond to a DCH subpoena. *Id.* at 11. However, he declined to reach the issue of whether Respondent ''is the 'alter ego' to Duncan Fordham and/or Duncan Drugs.'' *Id.* The Hearing Officer thus denied Respondent's appeal.

Respondent then appealed to the Superior Court for Richmond County, which heard the matter on January 12, 2007. On August 4, 2009, the court concluded that ''the evidence considered in the [DCH] hearing * * * was incomplete as the answer to Question 3 * * * on the application was not provided by the petitioner as a blank remained.'' Order on Petitioner's Appeal at 1, *Tereses* [sic], *Inc.,* v. *Department of Community Health,* No 2007RCCV0027 (Super. Ct. Ga., Aug. 4, 2009). The court also noted that Respondent ''had not yet furnished a Georgia Medicaid Disclosure of

[1] The District Court also ordered Fordham and Fordham, Inc., to pay an assessment of $400 and restitution of more than $1,000,000; the Court also ordered forfeited $500,000 to the United States. GX 15, at 5–6.

[2] The DI testified that while Mr. Fordham was released on bond, he attempted to sell the pharmacy although the indictment had included a count for forfeiture. Tr. 22–23. The DI also testified that following Duncan Drugs' exclusion from Medicaid, Fordham filled prescriptions for Medicaid patients and billed for the prescriptions by using another pharmacy's enrollment. *Id.* at 23.

There is no evidence, however, that the DI was personally involved in investigating either incident. Moreover, while her testimony is consistent with the findings made by a DCH Hearing Officer in Respondent's appeal of the denial of its application to be an authorized Medicaid Provider, *see* GX 8, at 2–3, that decision was subsequently vacated by the Superior Court of Richmond County, which itself is now on appeal to the Georgia Court of Appeals. Accordingly, the State Hearing Officer's findings are not entitled to preclusive effect.

[3] Respondent's DEA registration authorizes it to dispense controlled substances in schedules II through V; while the registration was to expire on March 31, 2009, on February 2, 2009, Respondent filed a renewal application. Because this application was filed more than 45 days before the expiration date as required by the Agency's rule, Respondent's registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i).

[4] Mr. Scharff testified that he answered ''no'' because he was ''thinking [of himself] as the pharmacist in charge and not anybody else.'' Tr. 78. He further explained that in South Carolina, the form ''specifically says, and any other member of the corporation,'' and that the Georgia form ''makes it sound like it's directed straight towards me.'' *Id.* at 78–79.

Ownership and Control Interest form.'' *Id.* Concluding that ''in the interest of justice and completeness, * * * the ALJ should have directed that the form be completed by the petitioner before ruling on the issue as presented,'' the court remanded the case ''for completion of the record'' and instructed the Hearing Officer to ''direct petitioner to complete the form.'' *Id.*

On September 8, 2009, the State filed an Application for Discretionary Appeal in the Georgia Court of Appeals. Notice of Appeal at 1. On October 1, the court granted the application. *Georgia Dep't of Community Health* v. *Terese's* [sic], *Inc.,* (Ga. App. Oct. 1, 2009) (order granting application for discretionary review). However, on June 24, 2010, the court dismissed the State's appeal for lack of jurisdiction. Order at 3, *DCH* v.*Terese's,* No. A10A0658s (order dismissing appeal).[5]

The DEA Investigation

A DEA Diversion Investigator (DI) testified that in May 2005, a person came into the DEA Augusta, Georgia office, and stated that ''he was able to go into Duncan Drugs and received drugs upon request and [that] the pharmacy * * * would apply it to DEA Registrations of physicians that never saw the individual.'' Tr. 19–20. The DI then contacted the U.S. Attorney's Office and was told that ''Duncan Drugs was under indictment for health care fraud.'' *Id.* at 20.

The DI further testified that she subsequently learned that Fordham ''supposedly * * * was involved with a contract'' which had ''an incentive clause'' under which ''he provided controlled substances or drugs to a mental health center'' and ''received millions of dollars, that they found * * * was fraudulent.'' *Id.* at 21–22. The DI then testified that Fordham was convicted of health care fraud. *Id.* at 22. The record contains no further evidence substantiating the allegation that Fordham had committed violations of the Controlled Substances Act (CSA).[6]

On some date which is not clear from the record, the DI learned from a Special Agent with the DCH that ''Duncan Drugs had opened up again.'' *Id.* at 31. She also learned that Respondent's application for a DEA registration had been approved and ''was surprised because'' she viewed Terese Fordham as ''an extension of Duncan Drugs.'' *Id.* at 27.

Thereafter, on April 21, 2006, the DI (along with the DCH Special Agent) met with Mr. Scharff at his residence to discuss Respondent's ''management structure.'' *Id.* at 28–29. According to the DI, Scharff stated that he owned 10 percent of the pharmacy (although he had not invested any money in Terese, Inc.) and Ms. Fordham owned 80 percent; Mr. Scharff was unsure as to who owned the remaining 10 percent. *Id.* at 34–35.

On May 4, 2006, the DI and the DCH Special Agent went to Respondent to interview Ms. Fordham regarding its management structure. *Id.* at 35–36. Because Ms. Fordham was not present upon the DI's arrival, the DI proceeded to conduct an inspection during which she reviewed Respondent's recordkeeping. *Id.* at 36. The DI found that Respondent had not been completing the right-hand side of the DEA Forms 222 (which are used to order schedule II controlled substances) to indicate when it had received the drugs. *Id.* The DI further found that Respondent did not have an initial inventory of its controlled substances, which it is required to make a record of even if no drugs are initially on hand.[7] *Id.* Finally, Respondent did not have a power of attorney form indicating who was authorized to order schedule II controlled substances on its behalf. *Id.* Regarding these violations, Mr. Scharff testified that he was ''derelict'' in failing to see that the order forms were signed and that upon being informed that this needed to be done, he ''immediately began doing it.'' *Id.* at 79–80.

Upon Ms. Fordham's arrival at the pharmacy, the DI questioned her regarding Respondent's management structure and whether Duncan Fordham was involved. *Id.* at 37, 40–41. Ms. Fordham stated that she owned 80 percent of the pharmacy, her daughter owned 10 percent and Mr. Scharff owned the remaining 10 percent. *Id.* at 37–38. Ms. Fordham stated that she had put up all of the money for the pharmacy.[8] *Id.* at 38. According to the DI, Ms. Fordham stated that she had opened the pharmacy because she was getting phone calls from Duncan Drugs' former customers and felt ''an obligation'' to its former employees ''to keep their jobs.'' *Id.* Moreover, in her testimony, Ms. Fordham stated that her husband had nothing to do with the business, Tr. 125, and there is no evidence in the record establishing that he had a financial or controlling interest in the pharmacy.

Discussion

The Government argues that ''there is a myriad of prior agency decisions to support a revocation on the grounds that the new registrant was intended to operate so as to avoid the consequence of the surrender of the previous family business.'' Gov. Br. 8. It contends that ''[u]nder 21 U.S.C. § 824(a)(4), the Deputy Administrator may revoke Respondent's registration on public interest grounds'' and that, in this matter, ''all of the five factors under 21 U.S.C. § 823(f) are relevant to the determination of whether Respondent's registration would be in the public interest.'' *Id.* at 9. The Government further maintains that its ''exhibits and testimony support by a preponderance of the evidence a finding that the Government has presented a case for revocation of [Respondent's] registration on public interest grounds.'' *Id.* at 11.

As noted above, the Government seeks the revocation of Respondent's DEA registration on public interest grounds because Ms. Fordham's spouse has been convicted of health care fraud; the Government also cites as a basis for revocation that Ms. Fordham falsified Respondent's application to become a Medicaid provider and declined to present evidence to the State as to the ownership of Respondent, thus resulting in the State's denial of its application. ALJ Ex. at 2. As explained below, the Government's assertion as to the scope of the Agency's authority under section 824(a)(4) is irreconcilable with the text, structure, and history of section 824, as well as 42 U.S.C. 1320a–7, which, because it is specifically referenced in section 824(a)(5), is also relevant here.

[5] On October 25, 2010, Respondent submitted a document establishing that it and the DCH had settled their dispute and that the DCH had granted it a Medicaid Provider number. However, there is no evidence that the document was served on the Government. Accordingly, I have not considered the document. Moreover, among the legal theories advanced by the Government is that the ''[p]redecessor pharmacy violated [s]tate laws involving Medicare [f]raud,'' and that this provides a basis to revoke Respondent's registration under the public interest standard. Gov. Br. at 10–11. Accordingly, the settlement does not moot the case.

[6] The DI also testified that while Duncan Fordham was out on bond, he used the Medicaid Provider number of another pharmacist to fill prescriptions that were dispensed by Duncan Drugs. Tr. 23. Beyond the fact that the DI's testimony does not appear to have been based on personal knowledge, here again, there is no evidence that any of the prescriptions violated the CSA.

[7] The DI explained that under the regulation, even if no drugs are on hand initially, an inventory indicating that there are no drugs is still required. Tr. 36; *see* 21 CFR 1304.11(b) (''In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.'').

[8] Ms. Fordham further testified that she obtained a loan for $280,000 from Smith Drug Company, a distributor, and took cash advances on her credit cards. Tr. 120–21. Ms. Fordham also acknowledged that she is not a licensed pharmacist and had never run a pharmacy. *Id.* at 131. However, she had worked as an assistant manager of a bank and owned a business. *Id.*

Notably, the Government does not address the applicability of section 824(a)(5) and 42 U.S.C. 1320a–7 in its brief, and its interpretation would render section 824(a)(5) meaningless.

The starting point in any case of statutory construction is the language of the statute itself. *See, e.g., Desert Palace, Inc.,* v. *Costa,* 539 U.S. 90, 98 (2003). In section 824(a), Congress enumerated the five grounds on which the Agency may suspend or revoke a registration issued under the Controlled Substances Act. The statute provides in relevant part:

> A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—
>
> (1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;
>
> (2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;
>
> (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;
>
> (4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or
>
> (5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.

21 U.S.C. 824(a).

As section 824(a)(4) makes clear, the scope of the Agency's authority to revoke on public interest grounds is defined by the factors set forth in 21 U.S.C. 823. In the case of a pharmacy, Congress directed that the following factors be considered ''[i]n determining the public interest'':

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing * * * controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

Contrary to the Government's assertions that all five factors are relevant here, none of its principal allegations fall within any of the factors. Gov. Br. 9. The Government cites no authority for its contention that the State's denial of Respondent's application to participate in Medicaid constitutes action by a ''State licensing board or professional disciplinary authority.'' 21 U.S.C. 823(f)(1), Gov. Br. 9. Moreover, while the Government cites the conviction of Duncan Drugs as ground to revoke under factor three, neither that entity, nor Mr. Fordham, was convicted of an offense related to the ''distribution[] or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). As for factors two and four, while the Government elicited testimony that an informant had told a DI that Duncan Drugs was filling unlawful prescriptions, this evidence does not rise to the level of substantial evidence,[9] and the only allegations proven on this record which are relevant in assessing Respondent's experience in dispensing controlled substances, *id.* § 823(f)(2), and its compliance with applicable laws related to controlled substances, *id.* § 823(f)(4), involve three minor recordkeeping violations. Thus, in determining whether Respondent's registration is ''inconsistent with the public interest,'' 21 U.S.C. 824(a), the only question remaining is whether the Government's allegations constitute ''[s]uch other conduct which may threaten public health and safety.'' *Id.* § 823(f)(5). I conclude that they do not.

As noted above, in section 824(a)(5), Congress provided the Agency with authority to revoke a registration where a registrant has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42. Under 42 U.S.C. 1320a–7, the Secretary of the Department of Health and Human Services has been granted the authority to exclude an individual or entity ''from participation in any Federal health care program.'' The statute provides for two distinct categories of exclusion: (1) Those which are ''mandatory,'' and (2) those which are ''permissive.'' *Compare id.* § 1320a–7(a) (''[t]he Secretary shall exclude''), *with id.* § 1320a–7(b) (''[t]he Secretary may exclude''). *See also* S. Rep. No. 100–109, at 4, *reprinted in* 1987 U.S.C.C.A.N. 682, 685 (''The bill identifies a number of acts for which exclusion from Medicare and State health care programs is appropriate. * * * The bill divides these actions into two broad categories: those for which exclusion is mandatory, and those for which it is discretionary with the Secretary.'').

The Secretary's ''mandatory exclusion'' authority is triggered, however, only when an ''individual or entity'' has been convicted of certain criminal offenses. 42 U.S.C. 1320a–7(a). Most importantly, Congress has limited this authority to four categories of offenses: (1) ''[c]onviction of program-related crimes,'' which is defined as ''a criminal offense related to the delivery of an item or service under * * * 42 U.S.C. §§ 1395 et seq. * * * or under any State health care program''; (2) ''[c]onviction relating to patient abuse,'' which is defined as ''a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service''; (3) ''[f]elony conviction relating to health care fraud,'' which is defined as a conviction ''under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in * * * [subparagraph (a)(1)]) operated by or financed * * * by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct''; and (4) ''[f]elony conviction relating to controlled substance,'' which is defined as a conviction, ''under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.'' *Id.*

By contrast, subsection b grants the Secretary ''permissive exclusion'' authority on fifteen different grounds. *Id.* § 1320a–7(b). Of potential relevance here, the Secretary's ''permissive exclusion'' authority includes where ''an individual or entity * * * has been suspended or excluded from participation under * * * any Federal program * * * involving the provision

[9] This evidence was limited to the testimony of a DI that in 2005, an informant told her that ''he was able to go into Duncan Drugs and received drugs upon request and [that] the pharmacy * * * would apply it to DEA Registration of physicians that never saw the individual.'' Tr. 19–20. The DI did not testify as to any investigation she conducted to corroborate the informant's story. This testimony thus creates only a suspicion that Duncan Drugs and/or Duncan Fordham were diverting controlled substances and does not rise to the level of substantial evidence. *See NLRB* v. *Columbia Enameling & Stamping Co., Inc.,* 306 U.S. 292, 300 (1939) (''Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established.'').

To make clear, had the evidence established that Duncan Fordham or Duncan Drugs violated the CSA or state controlled substance laws, the Agency case law on piercing the corporate veil would authorize the revocation of Respondent's registration.

of health care, or * * * a State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity,'' *Id.* § 1320a–7(b)(5), where an entity is ''controlled by a sanctioned individual,'' *Id.* § 1320a–7(b)(8),[10] and where an individual or entity has failed to ''fully and accurately make any disclosure required by [42 U.S.C. §§ 1320a–3, 1320a–3a, or 1320a–5].'' *Id.* § 1320a–7(b)(15).

As the foregoing demonstrates, in granting the Secretary authority to exclude providers from participating in Federal health care programs, Congress created two distinct categories of exclusion. When, however, in 1987 Congress amended section 304 of the Controlled Substances Act to authorize the Attorney General to suspend or revoke a registration based on a provider's having ''been excluded (or directed to be excluded) from participation in'' a Federal health care program, it provided that the exclusion must be ''pursuant to section 1320a–7(a).'' 21 U.S.C. 824(a)(5).

By its plain terms, section 824(a)(5) therefore limits the Attorney General's authority to revoke a registration based on an entity's exclusion from any Federal health care program to only those instances in which an individual or entity has been mandatorily excluded. *See* 42 U.S.C. 1320a–7(a). If Congress had intended that revocation of a DEA registration was warranted whenever a provider has been excluded from participation in a Federal health care program, it could have easily done so in the statutory text.

It is undisputed that both Duncan Fordham and the corporate entity, Fordham, Inc., were convicted of healthcare fraud in violation of 18 U.S.C. 1347. GXs 14 & 15. While Fordham and his corporation were terminated as a Medicaid provider by the Georgia DCH (and not the Secretary), it is clear that his and his corporation's respective convictions constitute a ''[f]elony conviction relating to health care fraud'' and fall within the Secretary's ''mandatory exclusion'' authority. 42 U.S.C. 1320a–7(a)(3).

It is also clear, however, that neither Terese Fordham nor Respondent has been convicted of any offense, let alone one which would subject them to the Secretary's mandatory exclusion authority. *See* 42 U.S.C. 1320a–7(a). Moreover, none of the other grounds which were alleged by the State for excluding Respondent from participation in Medicaid (providing materially false information, being the alter ego of Duncan Drugs, and failing to provide documentation requested by DCH, *see* GX 7, at 1), subjected it to mandatory exclusion by the Secretary. *See Id.* Indeed, even the allegation that Respondent is the alter ego of Duncan Drugs (and is controlled by Duncan Fordham) appears to have been specifically addressed by Congress in section 1320a–7(b)(8), which applies to ''[e]ntities controlled by a sanctioned individual.'' *Id.* § 1320a–7(b)(8).

However, as explained above, this ground falls within the Secretary's ''permissive exclusion'' authority and, as such, is outside of the scope of the Attorney General's authority under subsection 824(a)(5). 21 U.S.C. 824(a)(5). Moreover, the Government does not cite any decision of the Secretary holding that an entity that is deemed to be the alter ego of an entity which has been convicted of an offense subject to the ''mandatory exclusion'' authority is likewise subject to that authority.

The Government's brief does not address the applicability of subsection 824(a)(5) to its contention. However, in subsection 824(a)(5), Congress specifically addressed the circumstances in which an exclusion by the Secretary is grounds for the revocation of a DEA registration. As the Supreme Court has long explained, ''[a] specific provision controls over one of more general application.'' *Gozlon-Peretz* v. *United States,* 498 U.S. 395, 407 (1991) (citing *Crawford Fitting Co.* v. *J.T. Gibbons, Inc.,* 482 U.S. 437, 445 (1987)); *see also Bloate* v. *United States,* 130 S.Ct. 1345, 1354 (2010) (quoting *D. Ginsberg & Sons, Inc.* v. *Popkin,* 285 U.S. 204, 208 (1932) (''General language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment.'')). This rule of construction provides reason alone to reject the Government's assertion.

The Government's construction fails for other reasons. First, it ignores the history of the CSA. As originally enacted, the CSA limited the Attorney General's authority to revoke a registration to three circumstances: (1) Where a registrant had materially falsified an application for registration under either subchapter I (the CSA) or subchapter II (the Import and Export provisions, 21 U.S.C. 951–971); (2) where a registrant had been convicted of a felony under either subchapter I or II, ''or of any State [or other Federal law], relating to any substance defined in this title as a controlled substance''; and (3) where a registrant no longer has authority under State law to manufacture, distribute or dispense controlled substances. Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–515, § 304(a), 84 Stat. 1437, 1460 (1970) (codified as amended at 21 U.S.C. 824(a)).

Congress did not grant the Attorney General authority to revoke on public interest grounds until 1984, when it enacted the Drug Enforcement Amendments to the Comprehensive Crime Control Act of 1984. *See* Public Law 98–473, § 512, 98 Stat.1838, 2073 (1984). Congress then explained that the ''[i]mproper diversion of controlled substances by practitioners is one of the most serious aspects of the drug abuse problem. However, effective Federal action against practitioners has been severely inhibited by the limited authority in current law to deny or revoke practitioner registrations.'' H.R. Rep. No. 98–1030, at 266 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3448. Continuing, the House Report explained that:

> because of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants. Since State revocation of a practitioner's license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the State regulatory level have had a severe adverse impact on Federal anti-diversion efforts. The criteria of prior felony drug conviction for denial or revocation of registration has proven too limited in certain cases as well, for many violations involving controlled substances which are prescription drugs are not punishable as felonies under State law. Moreover, delays in obtaining conviction allow practitioners to continue to dispense drugs with a high abuse potential even where there is strong evidence that they have

[10] This paragraph provides that:

Any entity with respect to which the Secretary determines that a person—

(A)(i) who has a direct or indirect ownership or control interest of 5 percent or more in the entity or with an ownership or control interest (as defined in [42 U.S.C. 1320(a)(3)]) in that entity,

(ii) who is an officer, director, agent, or managing employee (as defined in [42 U.S.C. 1320a–5(b)]) of that entity; or

(iii) who was described in clause (i) but is no longer so described because of a transfer of ownership or control interest, in anticipation of (or following) a conviction, assessment, or exclusion described in subparagraph (B) against the person, to an immediate family member (as defined in subsection (j)(1)) or a member of the household of the person (as defined in subsection (j)(2)) who continues to maintain an interest described in such clause—

is a person—

(B)(i) who has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection;

(ii) against who a civil monetary penalty has been assessed under [42 U.S.C. 1320a–7a or 1320a–8];

(iii) who has been excluded from participation under a program under [42 U.S.C. 1395 *et seq.*] or under a State health care program.

42 U.S.C. 1320a–7(b)(8).

significantly abused their authority to dispense controlled substances.

Clearly, the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest.

Id. Accordingly, Congress amended section 824(a) ''to add to the current bases for * * * revocation[] or suspension of registration a finding that registration would be inconsistent with the public interest *on the grounds specified in 21 U.S.C. § 823.'' Id.* at 3449 (emphasis added).

The House Report thus makes clear that Congress's primary purpose in authorizing revocation based on the public interest was to provide an additional means for the Attorney General to *address diversion by practitioners.* This is also made clear by Congress's command that the public interest be ''determined under'' the factors set forth in 21 U.S.C. 823, most of which—in the case of a practitioner—require a nexus to controlled substances. *See* 21 U.S.C. 823(f) (directing the Attorney General to consider, *inter alia,* a registrant's ''experience in dispensing * * * controlled substances,'' its ''conviction record under * * * laws relating to the * * * dispensing of controlled substances,'' and its ''[c]ompliance with applicable * * * laws relating to controlled substances'').[11]

It was not until three years later when, as part of the Medicare and Medicaid Patient and Program Protection of 1987, Congress amended subsection 824(a) to grant the Attorney General authority to revoke a registration of any individual or entity subject to mandatory exclusion from Medicare and Medicaid (as well as other Federally funded health care programs). *See* Public Law 100–93, § 8(j), 101 Stat. 680, 695 (1987). *See also* S. Rep. No. 100–109, at 2, 1987 U.S.C.C.A.N. at 682–83 (''The Committee bill has four main elements. * * * First, the bill mandates the exclusion from Medicare and Medicaid of individuals convicted of program-related crimes or patient abuse or neglect. It also broadens the grounds for the discretionary exclusion of health care providers from Medicare and Medicaid. * * * *The Attorney General is authorized to deny, revoke, or suspend the controlled substances registration of any individual or entity subject to mandatory exclusion from Medicare.*) [12] (emphasis added).

Were the Government's interpretation correct that the Attorney General's authority under the public interest standard encompasses the allegations against Respondent, then Congress had no need to enact subparagraph (a)(5). Statutes, however, are not to be construed in a manner that renders their texts superfluous. *See Bloate,* 130 S.Ct. at 1355 (quoting *Duncan* v. *Walker,* 533 U.S. 167, 174 (2001) (''[A] statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'')). I therefore hold that the allegations that Respondent is the alter ego of Duncan Drugs, which has been convicted of health care fraud, as well as that Respondent materially falsified its state Medicaid application and did not disclose ownership information to the State, do not constitute ''such other conduct which may threaten public health and safety.'' 21 U.S.C. 823(f).

Accordingly, the allegations that Respondent is the alter ego of Duncan Drugs, which was convicted of health care fraud; that Respondent materially falsified its application to enroll in the Georgia Medicaid program; and that it failed to provide information requested by the DCH do not implicate any of the five public interest factors set forth in 21 U.S.C. 823(f), and thus do not provide a basis to conclude that Respondent has committed acts which render its registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Whether these allegations are grounds for the revocation of Respondent's DEA registration must be assessed under the legal standard which Congress specifically adopted in subparagraph (a)(5).[13]

Under this standard, however, even if DCH had proved the allegations, Respondent would not have been subject to ''mandatory exclusion'' by the Secretary pursuant to her authority under 42 U.S.C. 1320a–7(a), but rather only ''permissive exclusion'' pursuant to her authority under 42 U.S.C. 1320a–7(b). Accordingly, even if the DCH proceeding had resulted in Respondent's exclusion by the Secretary, because subparagraph (a)(5) unambiguously limits the Agency's revocation authority to where a registrant is subject to mandatory exclusion, the fact of permissive exclusion would not, by itself, provide a basis to revoke its DEA registration.

Indeed, the only substantial evidence in this record that Respondent (or for that matter, Duncan Drugs) ''has committed such acts as would render [its] registration under section 823 * * * inconsistent with the public interest,'' 21 U.S.C. 824(a)(4), is that pertaining to the three recordkeeping violations found during the May 2006 inspection. As found above, during the inspection, the DI found that Respondent did not have an initial inventory, *see* 21 CFR 1304.11(b), had not executed a power of attorney form to indicate who was authorized to order schedule II drugs on its behalf, *Id.* 1305.05(a), and had not been completing the DEA Forms 222 to indicate the dates on which it had received certain drugs. 21 CFR 1305.13(e).

Mr. Scharff, Respondent's Pharmacist-In-Charge, took responsibility for these deficiencies and was found by the ALJ to have credibly testified that they were corrected as soon as the DI brought them to his attention. ALJ at 23. Moreover, in its brief, the Government does not even cite these violations.

I therefore conclude that the Government has not proved that Respondent has committed acts which render its continued registration ''inconsistent with the public interest'' as that term has been defined by Congress for purposes of the CSA.[14] 21

[11] With respect to factor five—''other conduct which may threaten public health and safety''—DEA's case law has generally recognized that the misconduct must be related to controlled substances. *David E. Trawick,* 53 FR 5326, 5327 (1988). While there may be other acts, which do not directly involve controlled substances, but which threaten public health and safety and create reason to conclude that a person will not faithfully adhere to her responsibilities under the CSA, in light of Congress's clear statutory text and the history of the CSA, this case presents no occasion to consider the scope of actionable conduct under this factor.

[12] It acknowledged that in discussing Section 8 of the Medicare and Medicaid Patient and Program Protection Act, the Senate Report states that ''[t]he bill would amend the Controlled Substances Act to add exclusion from Medicare or a State health care program as a basis for the denial, revocation, or suspension of registration to manufacture, distribute or dispense a controlled substance.'' S. Rep. at 22, 1987 U.S.C.C.A.N. at 702. While this discussion is arguably read as indicating that Section 8 applied to both mandatory and permissive exclusions, legislative history cannot override a clear and unambiguous statutory text. *See United States* v. *Gonzales,* 520 U.S. 1, 6 (1997). (''Given the straightforward statutory command, there is no reason to resort to legislative history.'') (citation omitted).

[13] To make clear, where an allegation both implicates a public interest factor (or another of the Agency's revocation authorities), and also triggers the Secretary's permissive exclusion authority, DEA retains the authority to revoke under the applicable authority of 21 U.S.C. 824. Thus, while a misdemeanor conviction relating to controlled substances falls within the Secretary's permissive exclusion authority, *see* 42 U.S.C. 1320a–7(b)(3), DEA can still consider this conduct under the public interest standard. *See* 21 U.S.C. 823(f). Likewise, while the revocation or suspension of a physician's state medical license also falls within the Secretary's permissive exclusion authority, DEA can revoke the practitioner's registration under 21 U.S.C. 824(a)(3).

[14] The ALJ recommended, however, that Respondent's registration be ''subject to the condition that Mr. Fordham shall have no involvement with Respondent in any capacity,

U.S.C. 824(a)(4). However, I conclude that the recordkeeping violations warrant that Respondent be admonished, which shall be made a part of Respondent's official record with the Agency.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b), I order that Terese, Inc., d/b/a/Peach Orchard Drugs, be, and it hereby is, admonished. I further order that the application of Terese, Inc., to renew its DEA Certificate of Registration, be, and it hereby is, granted. This Order is effective immediately.

Dated: July 26, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–19556 Filed 8–2–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement: Curriculum Development for Women Offenders; Developing an Agency-Wide Approach

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) is seeking applications from organizations, groups or individuals to enter into a cooperative agreement for an 18-month period for the development and piloting of a curriculum specific to working with justice involved women. NIC has developed and delivered a number of training programs specific to management of women offenders. Each such program targets varied audiences and objectives, all with the common goal of improving justice system and individual outcomes for women offenders in the criminal justice system. Since the original ''Women Offenders: Developing an Agency-Wide Approach'' was delivered, significant findings specific to women have emerged, increasing our understanding of the risk, needs, and strengths of this population. This solicitation is for the development of a blended-learning curriculum that can be used to guide correctional leadership teams representing jails, prisons, and/or community corrections in planning an agency-wide process for the effective management of justice involved women. The curriculum will incorporate research-based information and will reflect adult learning theory using blended learning and Web-based technology.

DATES: Applications must be received by 4 p.m., E.D.T., August, 22, 2011.

ADDRESSES: Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street, NW., Room 5002, Washington, DC 20534. Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date.

Hand delivered applications should be brought to 500 First St., NW., Washington, DC 20534. At the front security desk, dial 7–3106, ext. 0 for pickup. Faxed or e-mailed applications will not be accepted. Electronic applications can only be submitted via *http://www.grants.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this announcement and links to the required application forms can be downloaded from the NIC Web site at *http://www.nicic.gov/cooperativeagreements.*

All technical or programmatic questions concerning this announcement should be directed to Maureen Buell, Correctional Program Specialist, National Institute of Corrections, Administrative Division. Ms. Buell can be reached directly at 1–800–995–6423 ext. 40121 or by e-mail at *mbuell@bop.gov.* In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *http://www.nicic.gov* for public review (the names of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation. Only questions received by 12 p.m. (E.D.T.) on August 17, 2011 will be answered.

SUPPLEMENTARY INFORMATION:

Overview: The curriculum ''Women Offenders: Developing an Agency Approach'' was originally developed in 2002 and since that time a number of program modules have been revised to reflect emerging information and practices. This curriculum has been offered to agency leaders with roles in developing and/or implementing policy within their organizations. The final product from this solicitation will reflect the emerging research and use a blended-learning format.

Over the past decade there have been significant contributions to correctional practices with evidence-based research and knowledge. More recently, emerging research has identified areas that contribute to women's risk in institutional and/or community corrections settings. Some of these areas include housing safety, history of family conflict, victimization as a child and adult, dysfunctional relationships, and parental stress among other areas. Also factored in are areas of strength and resiliency which, when applied properly, can contribute to an agencies' case management and supervision strategies with a focus remaining on staff, offender, institutional and community safety. Through the incorporation of this information in professional development programs, agencies can become better equipped to manage a population that has increased dramatically since the 1990s and brings a unique set of challenges yet present reduced levels of risk to correctional and community settings.

Background: Since the 1970s, rates of women's involvement in criminal justice has increased dramatically and more recently surpassed the rate at which men have been entering the system. From 1995 to 2005, the total number of female prisoners increased 57% compared to 34% increase for male prisoners (Harrison & Beck [2006] Prison and Jail Inmates at Midyear 2005 [NCJ Publication No. 213133]), primarily for drug and property related offenses. At years end 2008, 35% of women were serving sentences for violent offenses versus 53% of men; 29% of women were serving sentences for property crimes and 26% for drug-related crimes versus 17% of men for both property crime and drug offenses (BJS, West, H. and Sabol W, December 2010, NCJ 231675), respectively. Other state and federal legislation has had severe consequences for women with children in both incarcerative and community-based settings. The impact of these legislative changes is often not well understood by correctional policymakers. The Adoption and Safe Families Act of 1993, Temporary Assistance for Needy Families (TANF), and public housing restrictions are just some of the laws that have unintended consequences for justice-involved women. According to a 2009 report from Bureau of Justice Statistics, since 1991, the number of children with a mother in prison has more than doubled, up 131%, while the number of children with a father in prison has grown by 77%. This finding reflects a faster rate of growth in the number of mothers held

including ownership, management, or as an employee, and shall exercise no influence or control, direct or indirect, over the operation of Respondent.'' ALJ at 27. As noted above, in sentencing Duncan Fordham, the United States District Court ordered Duncan Fordham that ''he is not to be employed with or without compensation in any pharmacy.'' GX 15, at 4.