submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on September 19, 2023, Groff NA Hemplex LLC, 100 Redco Avenue, Suite A, Red Lion, Pennsylvania 17356–1436, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import the listed controlled substances in bulk form to manufacture research grade material for clinical trial studies. Several types of Marihuana Extract compounds are listed under drug code 7350. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–24575 Filed 11–6–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jagjit Kaleka, D.V.M.; Decision and Order

On February 25, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Jagjit Kaleka, D.V.M. (Respondent), of Mauston, Wisconsin. Request for Final Agency Action (RFAA), Government Exhibit (RFAAX) 13, at 1, 5. The OSC proposed the revocation of Respondent's DEA Certificate of Registration (registration), Control No. AK7830640, alleging that Respondent has ''committed such acts as would render [his] registration inconsistent with the public interest.'' *Id.* at 1, 2 (citing 21 U.S.C. 824(a)(4), 823(g)(1) [1]).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated April 6, 2023.[2]

I. Findings of Fact

According to the Declaration of a DEA Diversion Investigator (the DI), Respondent was the owner of and a veterinarian at Mauston Pet Hospital (the Pet Hospital). RFAA, Declaration of Diversion Investigator (Declaration), at 2. From June 21, 2019, through February 22, 2021, the Pet Hospital purchased 500 tablets of 10 mg oxycodone (Schedule II), 1000 tablets of 2 mg alprazolam (Schedule IV), and 100 tablets of 5 mg zolpidem (Schedule IV). *Id.; see also* RFAAX 2; RFAAX 9. On June 8, 2021, the DI served a Notice of Inspection at the Pet Hospital, and Respondent consented to an inspection of the premises. Declaration, at 2; *see also* RFAAX 7. Prior to the inspection, the DI asked Respondent to take an inventory of all controlled substances at the Pet Hospital,[3] and on the day of the inspection, the DI asked Respondent to produce a biennial inventory, which Respondent was unable to produce. Declaration, at 2, 4.

During the inspection, Respondent denied personally ordering the controlled substances in question, namely, oxycodone, alprazolam, and zolpidem. Declaration, at 2.[4] The DI explained that despite the Pet Hospital's purchases, ''[n]one of these drugs could be located on the premises and there were no records showing that the drugs had been dispensed, lost, stolen, or otherwise disposed of.'' *Id.* at 2, 3.[5] Further, ''[t]hough Respondent denied knowledge that [G.K., another practitioner at the Pet Hospital,] had been using the Pet Hospital's account to purchase and obtain controlled substances for other than a legitimate medical purpose in the usual course of veterinary practice, Respondent [admitted that he] was aware of at least one incident during which [G.K.] purchased and received alprazolam.'' *Id.*[6] Notably, Respondent admitted that

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[2] By letter dated March 14, 2022, Respondent requested a hearing. RFAAX 15, at 1. On May 16, 2022, Respondent withdrew his hearing request and Chief Administrative Law Judge John J. Mulrooney, II, issued an Order Terminating Proceedings. RFAAX 16; RFAAX 17.

[3] On June 6, 2021, Respondent emailed the DI a document titled ''Controlled Drug Inventory 5–25–2021.'' Declaration, at 4; *see also* RFAAX 6.

[4] As noted by the DI, the most recent invoice indicated that Respondent himself purchased 100 tablets of 2 mg alprazolam under his own DEA registration; all of the other invoices for the controlled substance purchases in question showed that the controlled substances were shipped to another practitioner at the Pet Hospital, G.K. *Id.* at 2–3; *see also* RFAAX 2, at 66; RFAAX 8, at 1; RFAAX 9, at 3. Respondent also admitted that his wife paid for all of the controlled substances ordered for the Pet Hospital. Declaration, at 3.

[5] Though unable to produce dispensing records for the controlled substances in question, Respondent was able to produce dispensing records for other controlled substances. *Id.* at 3; *see also* RFAAX 4. According to the DI, these other dispensing records were commingled with records of other practitioners, including G.K., and because the records lacked detail, the DI was unable to determine which controlled substances had been dispensed by Respondent. *Id.* Because there were no records showing the disposition of the oxycodone, alprazolam, or zolpidem in question, the DI was unable to confirm whether the drugs had been purchased for a legitimate medical purpose; moreover, there was no evidence that Respondent had contacted any law enforcement agency to report the diversion of any oxycodone, alprazolam, or zolpidem. Declaration, at 3.

[6] Respondent admitted to DI that he observed G.K. receiving a shipment of alprazolam in 2019; specifically, Respondent observed G.K. meet a delivery driver outside the Pet Hospital who gave G.K. several boxes that G.K. then placed in his personal vehicle. *Id.* Respondent stated that he then

neither alprazolam nor zolpidem have ever been used at the Pet Hospital for veterinary purposes. Declaration, at 3.

Although Respondent denied that he had any expired controlled substances, the DI found expired controlled substances in an unsecured area in the Pet Hospital's basement. *Id.* at 4; *see also* RFAAX 12. Respondent had no records of any disposal of expired or unwanted controlled substances, but Respondent told the DI that he disposed of expired or unwanted controlled substances by giving them to the police or placing them in the garbage, which the DI noted was an unacceptable method that does not render the controlled substances '' 'non-retrievable' '' pursuant to Federal regulations. Declaration, at 2, 4 (citing 21 CFR 1317.90(a)).[7] [8]

II. Discussion

A. The Five Public Interest Factors

Under the CSA, ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . 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.'' 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant]'s experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant]'s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),[9] the Government's evidence in support of its *prima facie* case for revocation of Respondent's registration is confined to Factors B and D. *See* RFAA, at 6–10.[10] Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government's evidence satisfies its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.,* 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Respondent violated numerous Federal laws regulating controlled substances. RFAAX 14, at 2–3. Specifically, Federal law requires that registrants (1) keep a biennial inventory of any controlled substances on hand; (2) keep controlled substances in a ''securely locked, substantially constructed cabinet''; (3) dispose of controlled substances properly so as to comply with applicable regulations and render the controlled substances non-retrievable; (4) keep records of the disposal of controlled substances; and (5) timely report any loss of controlled substances. 21 U.S.C. 827(a)–(b); 21 CFR 1301.75(b), 1301.76(b), 1304.11(a), 1304.11(c), 1304.21(e), 1317.90, and 1317.95.[11]

Here, the record demonstrates that Respondent, among other things, failed to conduct a biennial inventory of controlled substances, failed to properly store controlled substances in a securely locked, substantially constructed cabinet, failed to dispose of controlled substances properly so as to comply with applicable regulations and render the controlled substances non-retrievable, failed to keep records of the disposal of controlled substances, and failed to timely report the loss of controlled substances. As Respondent's conduct displays clear violations of the various Federal regulations described above, the Agency hereby sustains the Government's allegations that Respondent repeatedly violated Federal law relating to controlled substances.

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Respondent's registration and thus finds Respondent's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Respondent failed to provide sufficient evidence to rebut the Government's *prima facie* case.

instructed an employee, S.T., to retrieve the boxes and bring them inside Pet Hospital where Respondent confirmed that they contained alprazolam. *Id.* In addition, S.T. admitted to filling out a DEA form 222 for the purchase of oxycodone at G.K.'s request. *Id.* at 4; *see also* RFAAX 2, at 3; RFAAX 3.

[7] The DI referenced 21 CFR 1317.90(a) once more in noting that ''because Respondent was not the 'ultimate user[]' or '[a] person[] lawfully entitled to dispose of an ultimate user's decedent's property,'[] he did not dispose of the controlled substances 'in compliance with applicable Federal, State, tribal[], and local laws and regulations.' '' *Id.* at 4.

[8] The DI also described how Respondent had been previously notified of violations in 2017, with Respondent at that time cited by DEA for failing to keep a biennial inventory, failing to maintain separate and readily retrievable records of controlled substances, failing to keep controlled substances in a securely locked, substantially constructed cabinet, and accepting controlled substances from end users without being licensed as a collector. *Id.* at 2, 4–5; *see also* RFAAX 10. Respondent was also subject to disciplinary action by the State of Wisconsin Veterinary Examining Board in 2018 following findings that Respondent had failed to store controlled substances in a securely locked, substantially constructed cabinet, had failed to keep a biennial inventory, and had sold a Schedule III controlled substance to an unregistered individual who had previously surrendered his DEA registration and was not authorized to possess or purchase controlled substances. Declaration, at 2, 5; *see also* RFAAX 11.

[9] As to Factor A, the Agency considers the recommendation of the appropriate state licensing board. Here, the state licensing board has taken disciplinary action against Respondent's veterinary license arising out of similar misconduct as that which forms the basis for the OSC in the current matter. *See* RFAAX 11; RFAAX 14, at 3. Nonetheless, because the Government has not made any representations as to Factor A in its RFAA, the Agency finds that Factor A weighs neither for nor against Respondent's continued registration. As to Factor C, there is no evidence in the record that Respondent has been convicted of an offense under either Federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.* Finally, as to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Respondent.

[10] In its RFAA, the Government noted that if the Agency were to find that Factors B and D did not weigh against Respondent's continued registration, it would rely on Factor E in the alternative. *Id.* at 6.

[11] Federal law also prohibits an individual from accepting controlled substances from end users without being authorized as a collector. 21 U.S.C. 822(g)(1)(A) (incorrectly cited in the OSC as 21 U.S.C. 821(g)(1)(A), *see* RFAAX 14, at 3); 21 CFR 1317.30 and 1317.40.

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021).

Here, although Respondent initially requested a hearing, he withdrew his hearing request and did not otherwise avail himself of the opportunity to refute the Government's case. As such, Respondent has made no representations as to his future compliance with the CSA nor made any demonstration that he can be entrusted with registration. In fact, despite having already been subject to state action and a Federal citation in 2017 and thus put on notice of the impropriety of his actions, Respondent failed to change his ways and continued to commit much of the same misconduct. Moreover, the evidence presented by the Government clearly shows that Respondent violated the CSA, further indicating that Respondent cannot be entrusted. Accordingly, the Agency will order the revocation of Respondent's registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. AK7830640 issued to Jagjit Kaleka, D.V.M. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Jagjit Kaleka, D.V.M., to renew or modify this registration, as well as any other pending application of Jagjit Kaleka, D.V.M., for additional registration in Wisconsin. This Order is effective December 7, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 31, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–24524 Filed 11–6–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1285]

Importer of Controlled Substances Application: Mylan Technologies Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Mylan Technologies Inc. as applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before December 7, 2023. Such persons may also file a written request for a hearing on the application on or before December 7, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 5, 2023, Mylan Technologies Inc. 110 Lake Street, Saint Albans, Vermont 05478–2266 applied to be registered as an importer of the following basic class(es) of controlled substance(s)

Controlled substance	Drug code	Schedule
Fentanyl	9801	II
Methylphenidate	1724	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically manufactured FDF to foreign markets. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–24573 Filed 11–6–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Modification to Consent Decree Under the Clean Water Act

On October 25, 2023, the Department of Justice lodged a proposed a Material Modification to the Consent Decrees' Wet Weather Improvement Program (''Modification'') with the United States District Court for the Southern District