Issued: October 5, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–22321 Filed 10–7–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1188]

Certain Pick-Up Truck Folding Bed Cover Systems and Components Thereof; Commission Determination Not To Review an Initial Determination Terminating the Investigation Based Upon Withdrawal of the Complaint; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the ''Commission'') has determined not to review an initial determination (''ID'') (Order No. 18) granting complainants' motion to terminate the present investigation in its entirety based on withdrawal of the complaint. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: On December 30, 2019, the Commission instituted the present investigation on a complaint, as supplemented, filed by Extang Corporation and Laurmark Enterprises, Inc. (d/b/a Bak Industries) (collectively, ''Complainants''), both of Ann Arbor, Michigan. 84 FR 71975–76 (Dec. 30, 2019). The complaint alleges a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''Section 337''), in the importation, sale for importation, and sale in the United States after importation of certain pick-up truck folding bed cover systems and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 7,484,788 and 8,061,758 (''the 758 patent''). *Id.* The complaint further alleges that an industry exists in the United States. *Id.*

The notice of investigation names the following parties as respondents: Tyger Auto Inc. of Rialto, California; Cixi City Liyuan Auto Parts Co. of Zhejiang Province, China; and Hong Kong Car Start Industries Co., of Zhijian Province, China (collectively, ''Respondents''). *Id.* The notice of investigation also names the Office of Unfair Import Investigations (''OUII'') as a party. *Id.*

On March 18, 2020, the presiding administrative law judge (''ALJ'') issued an ID (Order No. 6), granting Complainants' unopposed motion to amend the complaint and notice of investigation in order to supplement and clarify the allegations of the original complaint and notice of investigation regarding the 758 patent. The Commission determined not to review the ID. Comm'n Notice (April 17, 2020).

On September 22, 2020, the ALJ issued the subject ID (Order No. 18) granting Complainants' unopposed motion to terminate the investigation in its entirety based upon the withdrawal of the complaint. The ALJ finds no extraordinary circumstances that would prevent termination of this investigation, and no agreements, written or oral, express or implied, between the parties concerning the subject matter of the investigation. The ALJ also granted Complainants' request to stay the procedural schedule pending final resolution of this ID.

No party filed a petition for review of Order No. 18.

The Commission has determined not to review the subject ID. The investigation is terminated in its entirety.

The Commission voted to approve this determination on October 2, 2020.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 2, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–22230 Filed 10–7–20; 8:45 am]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Committee on Rules of Practice and Procedure; Meeting of the Judicial Conference

AGENCY: Committee on Rules of Practice and Procedure, Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold a virtual meeting on January 5, 2021. The meeting is open to the public. When a meeting is held virtually, members of the public may join by telephone conference to listen but not participate. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.*

DATES: January 5, 2021, TIME: 10 a.m.–5 p.m. (Eastern).

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Secretary, Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, Thurgood Marshall Federal Judiciary Building, One Columbus Circle, NE, Suite 7–300, Washington, DC 20544, Telephone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

Authority: 28 U.S.C. 2073.

Dated: October 5, 2020.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2020–22326 Filed 10–7–20; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Wayne Pharmacy; Decision and Order

On March 30, 2018, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause (hereinafter, OSC) to Wayne Pharmacy (hereinafter, Registrant), which proposed the revocation of its DEA Certificate of Registration BW8625785. Government's Request for Final Agency Action Exhibit (hereinafter, RFAAX) 2 (OSC). The OSC alleged that Registrant's ''continued registration is inconsistent with the public interest.'' OSC, at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)). The OSC also proposed to deny any pending application by Registrant for renewal as

well as applications for new DEA registrations. *Id.*

In response to the OSC, Registrant issued a timely request for an administrative hearing, RFAAX 14 (Order Terminating Proceedings), and a hearing was scheduled for July 17, 2018. *Id.* On July 6, 2018, DEA and Registrant reached an administrative settlement, which required, among other things, for Registrant to admit to Paragraphs 2 through 8 of the OSC and to withdraw its request for a hearing. RFAAX 12 (Memorandum of Agreement), at 2–3. On July 9, 2018, pursuant to the settlement, Registrant withdrew its request for an administrative hearing. RFAAX 14.

On September 21, 2018, the Government forwarded a Request for Final Agency Action, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering its continued registration inconsistent with the public interest. Accordingly, I conclude that the appropriate sanction is for Registrant's DEA registration to be revoked.

I. Findings of Fact

A. DEA Registration

Registrant is registered with DEA as a retail pharmacy authorized to handle controlled substances in schedules II–V under DEA Registration No. BW8625785, with a registered location of 1055 Hamburg Turnpike, Wayne, New Jersey, 07470. RFAAX 1 (DEA Certificate of Registration). Registrant is owned by Barbara Kleiber (hereinafter, the Owner). *Id.;* RFAAX 13 (May 31, 2018 Prehearing Ruling), at Stipulation No. 2.

B. Administrative Settlement and Registrant's Admissions

In lieu of an administrative hearing on this matter, Registrant and the Government came to an administrative settlement, the terms of which were memorialized in a Memorandum of Agreement (hereinafter, MOA). RFAAX 12. As part of the settlement, Registrant, and its Owner, both ''accepted responsibility for their misconduct and for their failure to comply with federal laws pertaining to controlled substances as alleged in the [OSC].'' *Id.* at 2. Specifically, the Owner, both in her individual capacity and in her capacity as the owner of Registrant, admitted to the following factual allegations made in paragraphs 2 through 8 of the OSC against Registrant:

(1) Registrant is owned by Barbara Kleiber. M.B.[1] is a former employee of Registrant and the son of the Owner;

(2) In May 2017, Registrant's Pharmacist-in-Charge (''PIC'') Deborah Clark reported to the Wayne Police Department that in the course of investigating the loss of a bottle of oxycodone 30mg, she had conducted an audit and discovered that approximately 47,000 tablets of oxycodone 30mg were missing.

(3) Although Registrant became aware of the loss of 47,000 tablets of oxycodone 30mg in May 2017, Registrant did not file a DEA 106 notice of theft or loss until June 14, 2017, after DEA conducted its own inspection of Registrant, and in violation of 21 CFR 1301.76(b).

(4) On June 1, 2017, DEA inspected Registrant's records pursuant to a Notice of Inspection. During this inspection, an audit was conducted covering the May 1, 2015 to June 1, 2017 time period. DEA's audit of Registrant's records found that Registrant committed systematic violations of the Controlled Substances Act (hereinafter, CSA), 21 U.S.C. 801 *et seq.,* and DEA regulations, including the following:

a. Registrant's inventories resulted in inaccurate inventories in violation of 21 CFR 1304.22(c).

i. For the audit period, Registrant was accountable for 543,575 tablets of oxycodone 30 mg, but could only account for 510,994 tablets, a shortfall of 32,581 tablets.

ii. For the audit period, Registrant was accountable for 120,102 tablets of oxycodone/acetaminophen 10/325 mg, but could only account for 96,102, a shortfall of 24,000 tablets.

iii. For the audit period, Registrant was accountable for 41,004 tablets of Morphine IR 30 mg, but could only account for 34,487 tablets, a shortfall of 6,517 tablets.

(5) On September 18, 2017, DEA conducted an additional review of Registrant's records pursuant to an Administrative Inspection Warrant. DEA's audit of Registrant's records found that Registrant continued to commit systematic violations of the CSA and DEA regulations.

a. The five controlled substances that were audited on June 1, 2017, were again audited with an audit period of June 1, 2017 to September 18, 2017. Registrant's inventory continued to be inaccurate in violation of 21 CFR 1304.22(c).

i. For the audit period, Registrant was accountable for 44,954 tablets of oxycodone 30 mg, but could only account for 44,626 tablets, a shortfall of 328 tablets.

ii. For the audit period, Registrant was accountable for 12,389 tablets of oxycodone/acetaminophen 10/325 mg, but could only account for 12,193 a shortfall of 196 tablets.

iii. For the audit period, Registrant was accountable for 2,557 tablets of Morphine IR 30 mg, but could only account for 2,354 tablets, a shortfall of 203 tablets.

b. In addition to auditing the same controlled substances that were audited on June 1, 2017, DEA conducted an audit of additional controlled substances. For these additional controlled substances, the audit period was May 1, 2017 to September 18, 2017. Registrant's inventory was inaccurate with respect to these controlled substances in violation of 21 CFR 1304.22(c).

i. For the audit period, Registrant was accountable for 4,428 tablets of alprazolam 2 mg, but could only account for 3,318 tablets, a shortfall of 573 tablets.

ii. For the audit period, Registrant was accountable for 880 tablets of Tylenol with codeine #4, but could only account for 812 tablets, a shortfall of 68 tablets.

iii. For the audit period, Registrant was accountable for 2,487 tablets of Adderall IR 30 mg, but could only account for 2,292 tablets, a shortfall of 195 tablets.

(6) In December 2017, Registrant hired its own auditor to inspect its records. Using the audit period of January 1, 2017, to December 19, 2017, Registrant's own auditor found significant shortages. Specifically, Registrant's auditor found that during this time period, Registrant could not account for 15,264 tablets of oxycodone 30 mg, 13,966 tablets of oxycodone 15 mg, 4,140 tablets of alprazolam 2 mg, and 1,192 tablets of Adderall (generic) 30 mg.

(7) When the DEA conducted its audit on June 1, 2017, the Owner told DEA that Registrant was in the process of improving its practices since discovering the massive shortages that caused Registrant to report missing oxycodone to the Wayne Police Department. Specifically, the Owner advised DEA that Registrant was in the process of taking additional security measures; namely (1) ordering of a safe to store controlled substances (as opposed to the locked glass cabinet currently in use); and (2) tallying daily inventories of controlled substances. Neither of these alleged additional safeguards were effective, as the controlled substances continued to be stored in such a way that all employees

[1] I have used initials to refer to all of Registrant's employees except for the Pharmacist in Charge.

had access to them, and the daily inventories were conducted in such a way that any employee could alter the inventory. As such Registrant, on an ongoing basis, failed to adequately secure its controlled substances in violation of 21 CFR 1301.71.

The Owner and Registrant also both admitted that ''[the Owner] was given notice by DEA that there was reasonable basis to believe that [M.B.] was diverting controlled substances, but [the Owner] did not terminate [M.B.]'s employment for at least four months.'' RFAAX 12, at 2–3.

C. Government's Allegations

In addition to the factual allegations the Registrant admitted in the MOA, the Government has also alleged that M.B., the son of Registrant's owner and a former employee of Registrant, was involved in the theft of controlled substances from Registrant and that Registrant failed to terminate M.B. in the face of evidence that he was diverting controlled substances. OSC, at 4–5; RFAA, at 9–10. To support this allegation, the Government submitted recordings and transcripts of interviews the Wayne Police Department conducted with one of Registrant's Pharmacists and its PIC (which were also attended by DEA officers and investigators), RFAAX 5–9; text messages between Registrant's PIC and a DEA Task Force Officer (hereinafter, TFO One), RFAAX 11, 16; and the declaration of a DEA Diversion Investigator (hereinafter, DI One), who recounted conversations he had with Registrant's employees, owner, and representatives. RFAAX 15.

On June 1, 2017, DEA conducted an inspection at Registrant. DI One stated that he interviewed one of Registrant's pharmacy technicians, who recounted to him an incident from 2016, in which she discovered a trail of oxycodone tablets leading toward the restroom immediately after M.B. was involved in counting oxycodone tablets and then left for the restroom. GX 15, at 2.

On June 2, 2017, the Wayne Police Department interviewed a former pharmacist at Registrant, C.R. RFAAX 6 (Recording of C.R. Interview) and 7 (Transcript of C.R. Interview); *see also* RFAAX 16 (Declaration of TFO One). TFO One attended and participated in the interview. RFAAX 16. During the interview, C.R. described an incident he had with M.B. when C.R. was working as a pharmacist at Registrant and M.B. was working as a pharmacy technician. RFAAAX 7, at 12–13. C.R. stated that he caught M.B. putting a bottle of morphine sulfate 30 mg in his pocket. *Id.* C.R. said he confronted M.B., and M.B. produced the bottle from his pocket. *Id.* C.R. stated that after the pharmacy closed that night, he told the Owner about the incident. *Id.*

The Wayne Police Department interviewed Registrant's PIC, Deborah Clark, on June 9, 2017 and June 14, 2017. RFAAX 5 (Recordings of PIC interviews), 8 (Transcript of June 9 PIC Interview), 9 (Transcript of June 14 PIC Interview); *see also* RFAAX 15, at 2. DI One attended the June 9 interview. RFAAX 15, at 2. During the June 9 interview, PIC Clark reported an incident from May 4, 2017, where M.B. was involved in putting away an order at the pharmacy, which included six bottles of oxycodone. RFAAX 8, at 12. According to PIC Clark, M.B. abruptly left the pharmacy, and, after he left the pharmacy, a bottle of oxycodone was found to be missing. *Id.* When M.B. returned to the pharmacy, he appeared, in PIC Clark's opinion, to be ''spacey.'' *Id.* PIC Clark reported the missing bottle to the Owner. *Id.*

DI One also declared that DEA repeatedly told Registrant that there was a reasonable basis to believe that M.B. was diverting controlled substances. RFAAX 15, at 4. DI One stated that he told the Owner during the September 2017 audit that DEA believed her son, M.B., was diverting controlled substances. *Id.* DI One also said he was present ''at a meeting between representatives of the Department of Justice, DEA and [Registrant] which took place on January 8, 2018 and February 7, 2018,'' and ''[a]t both of those meetings [Registrant]'s representatives were told that [M.B.] was involved in diversion of controlled substances'' and at both of those meetings ''[Registrant]'s representatives indicated that [M.B.] still worked at Wayne Pharmacy.'' *Id.*

II. Discussion

A. Registrant's Registration Is Inconsistent With the Public Interest

Under the Controlled Substances Act, ''[a] registration . . . to . . . distribute[ ] or 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)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

(2) The [registrant]'s experience in dispensing . . . controlled substances.

(3) The [registrant]'s conviction record under Federal or State laws relating to the . . . 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). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharm., LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has met its *prima facie* case, the burden then shifts to the registrant to show that revoking registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

In this matter, while I have considered all of the Factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two, Four, and Five. I find the

Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

1. Factors Two and/or Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

As already discussed, pursuant to section 304 of the CSA, in conjunction with section 303 of the CSA, I am to consider evidence of Registrant's compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances in determining whether Registrant's continued registration is ''consistent with the public interest.'' 21 U.S.C. 824(a)(4). ''[A] registrant's 'ignorance of the law is no excuse' for actions that are inconsistent with responsibilities attendant upon a registration.'' *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,809 (2015) (quoting *Sigrid Sanchez, M.D.,* 78 FR 39,331, 39,336 (2013)). Instead, ''[a]ll registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules.'' *Id.* at 74,809 (internal citations omitted). Further, the Agency has consistently concluded that a pharmacy's registration is subject to revocation due to the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, LLC,* 69 FR 63,178, 63,181 (2004); *Plaza Pharmacy,* 53 FR 36,910, 36,911 (1988).

In support of its contention that Registrant's continued registration is inconsistent with the public interest, the Government has alleged that Registrant violated several federal laws related to controlled substances. Specifically, the Government has alleged that Registrant violated its recordkeeping obligations under the CSA, as implemented in 21 CFR 1304.22(c), to maintain accurate inventories of its controlled substances. The Government also alleged that Registrant violated 21 CFR 1301.71 and 1301.76 by failing to adequately secure its controlled substances and failing to timely notify DEA after Registrant discovered it was missing controlled substances.

A. Recordkeeping Allegations

Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances. *Grider Drug 1 & Grider Drug 2,* 77 FR 44,070, 44,100 (citing *Paul H. Volkman,* 73 FR 30,630, 30,644 (2008)). DEA decisions have explained that ''a registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances.'' *Volkman,* 73 FR at 30,644. Under the Act, ''every registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him.'' 21 U.S.C. 827(a). The CSA's implementing regulations specify at 21 CFR 1304.22(c) the records that a dispenser, such as Registrant, is required to maintain regarding the controlled substances it receives and dispenses.

Registrant's records were audited twice by DEA—on June 1, 2017 and September 18, 2017—and once by an auditor hired by Registrant in December 2017. As Registrant admitted in its MOA with the Government, each audit found significant shortages in Registrant's inventories of controlled substances. A shortage in an inventory audit of controlled substances occurs when a pharmacy is unable to account for all of the controlled substances it should have in its inventory.

It is clear from the shortages that Registrant was not maintaining required records. Accordingly, I find the unrefuted evidence supports a finding that Registrant violated its recordkeeping obligations under the CSA. This finding weighs against entrusting Registrant with a registration.

B. Security Controls Allegations

The Government alleged that Registrant violated 21 CFR 1301.71 and 1301.76(b) by failing to promptly report the loss of 47,000 tablets of oxycodone 30mg to DEA. 21 1301.76(b) requires registrants to notify its area DEA Field Division Office of ''the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft'' and to submit a DEA Form 106 regarding the loss or theft. The regulation provides factors to determine whether a loss is ''significant,'' which include ''the actual quantity of controlled substances lost in relation to the type of business,'' and ''[w]hether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals.'' 21 CFR 1301.76(b).

Registrant admitted that it became aware of the loss of 47,000 tablets of oxycodone 30mg in May 2017. The loss of such a large number of tablets of oxycodone, a schedule II controlled substance, is clearly significant under the factors listed in 21 CFR 1301.76(a). Registrant was required to report this significant loss of controlled substances within one business day of discovering the loss. Registrant, however, did not file a DEA 106 notice of theft or loss until June 14, 2017, after DEA conducted its own inspection of Registrant. Registrant's failure to notify DEA of the significant loss of controlled substances within one business day of discovering the loss was a violation of 21 CFR 1301.76(b) and a violation of 21 CFR 1301.71, which requires all registrants to provide ''effective controls and procedures to guard against theft and diversion of controlled substances'' as set forth in 1301.72–76.

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

Under Factor Five, the Administrator is authorized to consider ''[s]uch other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). Although Factor Five is broad, DEA decisions have qualified its breadth by limiting the considerations made under that factor to those where there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,141 (2012) (citing *Tony T. Bui,* 75 FR 49,979, 49,988 (2010)). As the Agency has previously stated, '''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify' the revocation of an existing registration or the denial of an application for a registration.'' *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,725 n.43 (2017) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998)).

The uncontested evidence in this case shows that Registrant was losing large quantities of controlled substances from its inventory and that these losses continued even when Registrant knew about the losses and therefore could have taken measures to stop them. After the DEA's June 2017 audit, Registrant was unquestionably aware that it was losing large quantities of controlled substances, but the DEA's September 2017 audit and the December 2017 audit conducted by Registrant's auditor show that Registrant continued to lose significant quantities of controlled substances throughout 2017. Furthermore, Registrant's employees had reported at least three incidents to Registrant's owner where it appeared to the employee that M.B. had stolen controlled substances from Registrant or where the employee had thwarted M.B.'s attempt to steal controlled

substances from the pharmacy. DEA also told Registrant on three separate occasions that there was a reasonable basis to believe that M.B. was diverting controlled substances. Despite these reports, Registrant continued to employ M.B. until at least February 2018.

There is also no evidence on the record that Registrant took any real measures to increase security at the pharmacy or otherwise stop the losses. Registrant's owner told DEA on June 1, 2017, that Registrant was in the process of taking additional security measures—namely ordering a safe to store controlled substances and taking daily inventories of controlled substances—and that M.B. no longer worked at Registrant. RFAAX 15, at 2. Registrant's PIC, however, told DEA on July 27, 2017, that Registrant's narcotics were being stored in an unlocked case and that any pharmacy employee could change the inventory quantities in Registrant's computer. RFAAX 11 (text messages between PIC and DEA TFO). Registrant also admitted that ''[n]either of these alleged additional safeguards were effective, as the controlled substances continued to be stored in such a way that all employees have access to them, and the daily inventories were conducted in such a way that any employee could alter the inventory.'' RFAAX 12, at 2 (admitting to the factual allegations in paragraphs 2–8 of the OSC); OSC, at 4. Furthermore, PIC Clark told the DEA that, as of July 27, 2017, M.B. was working as a pharmacy tech at Registrant. RFAA 11. Registrant confirmed that M.B. was still employed by Registrant in meetings with DEA on January 8, 2018 and February 7, 2018. RFAAX 15, at 4.

''[A] DEA registrant is obligated at all times to act in the public interest.'' *Peter F. Kelly, D.P.M.,* 82 FR 28,676, 28,688 (2017). Registrant's failure to take action to stop the illicit flow of controlled substances out of the pharmacy was a breach of its duty as a registrant to act in the public interest. Moreover, it likely permitted the additional diversion of hundreds (if not thousands) of units of controlled substances. I, therefore, find that Registrant's failure to stem the known diversion of controlled substances from its inventory constitutes ''conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5).

Having considered all of the factors, I conclude that the evidence pertinent to factors two, four, and five demonstrate a *prima facie* showing that Registrant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further conclude that Registrant has not rebutted the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why it can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales,* 546 U.S. at 259. ''Because 'past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23,853; *John H. Kennnedy, M.D.,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Registrant accepted responsibility for most of its misconduct in the MOA, in which it admitted to many of the factual allegations in the OSC in exchange for certain agreements from the Government. Registrant, however, did not present any evidence of remorse for its past misconduct and did not provide any assurances that it would not engage in such conduct in the future. Further, it provided no evidence of rehabilitative actions taken to correct its past unlawful behavior, except an agreement from the Owner, in her individual capacity, that ''she will not serve as an officer, partner, stockholder, proprietor, owner, partial owner, or pharmacist in charge of any entity that either possesses or is seeing a DEA Certificate of Registration'' for so long as the MOA between the Government and Registrant remains in effect. Absent such evidence and such assurances in this matter, I find that continued registration of Registrant is inconsistent with the public interest. Registrant's silence weighs against its continued registration. *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,142 (2012) (citing *Med. Shoppe-Jonesborough,* 73 FR at 387); *see also Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007).

Accordingly, I find that the factors weigh in favor of sanction and I shall order the sanction the Government requested, as contained in the Order below.

IV. 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 BW8625785 issued to Wayne Pharmacy. This Order is effective November 9, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–22216 Filed 10–7–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–642]

Importer of Controlled Substances Application: MMJ Biopharma Cultivation, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 9, 2020. Such persons may also file a written request for a hearing on the application on or before November 9, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: