

General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2737. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket information system (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: The Commission instituted the present investigation on February 12, 2021, based on a complaint and supplement thereto filed by Samsung Electronics Co., Ltd. of Gyeonggi-do, Korea and Samsung Electronics America, Inc. of Ridgefield Park, New Jersey (collectively, "Complainants"). 85 FR 9370-71 (Feb. 12, 2021). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation, sale for importation, and sale in the United States after importation of certain wireless communications equipment and components thereof by reason of infringement of certain claims of U.S. Patent No. 9,041,074; U.S. Patent No. 9,521,616; U.S. Patent No. 9,736,772; and U.S. Patent No. 10,797,405. *Id.* at 9371. The complaint further alleged that an industry in the United States exists or is in the process of being established, as required by section 337. *Id.* The notice of investigation named Ericsson AB of Stockholm, Sweden, and Telefonaktiebolaget LM Ericsson of Stockholm, Sweden, and Ericsson Inc., of Plano, Texas. *Id.*

On May 14, 2021, the parties filed a joint motion to terminate the investigation based on settlement. The parties represent that "there are no other agreements, written or oral, expressed or implied between Samsung and Ericsson concerning the subject matter of the investigation." *See ID* at 2.

On June 10, 2021, the presiding administrative law judge issued Order No. 9, granting the joint motion to terminate the investigation. The ID finds that the motion complies with the requirements of Commission Rule 210.21(19 CFR 210.21) and there will not be a negative impact on the public interest. No party filed a petition for review of the ID.

The Commission has determined not to review this ID. The investigation is terminated.

The Commission vote for this determination took place on June 28, 2021.

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: June 28, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021-14149 Filed 7-1-21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Spring Valley Family Pharmacy; Decision and Order

On April 12, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Spring Valley Family Pharmacy (hereinafter, Registrant) of Gallipolis, Ohio. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration (hereinafter, registration) No. FS7068249. *Id.* It alleged that Registrant "currently lacks state authority to handle controlled substances." *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about October 2, 2020, Registrant permanently and voluntarily surrendered its Ohio state pharmacy license to the State of Ohio Board of Pharmacy with the surrender effective on October 5, 2020. *Id.* at 2. According to the OSC, Registrant permanently and voluntarily surrendered its Ohio state pharmacy license "after its owner and primary operator, Brandon O'Callaghan, permanently and voluntarily surrendered his state pharmacist license after testing positive for controlled substances in violation of a Board Order." *Id.* The OSC concluded that because Registrant is "currently without authority to handle controlled substances in Ohio, the state in which [Registrant] is registered with DEA. . . . DEA must revoke [Registrant's] registration. . . ." *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written

statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2-3 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated June 8, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Charleston District Office, Louisville Field Division, stated that she and a Tactical Diversion Squad Group Supervisor traveled to the residence of Brandon O'Callaghan, the former owner and pharmacist for Spring Valley Family Pharmacy, in Winfield, West Virginia on April 26, 2021. Request for Final Agency Action, dated June 9, 2021 (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 3 at 1. The DI stated that on that date, she "personally handed Mr. O'Callaghan a copy of the [OSC]." *Id.* The DI also stated that "Mr. O'Callaghan signed Form DEA-12 Receipt for Cash or Other Items, which indicated that he received a copy of the [OSC]." *Id.* In her Declaration, the DI included a true and correct copy of the DEA-12 that Mr. O'Callaghan signed. RFAAX 3, Appendix (hereinafter, App.) A.

The Government forwarded its RFAA, along with the evidentiary record, to this office on June 10, 2021. In its RFAA, the Government represents that "[Registrant] has not submitted a timely request for a hearing in this matter." ¹ RFAA, at 1.

The Government seeks to "revoke the [DEA COR] of [Registrant] because [Registrant] lacks authority to handle controlled substances in the State of Ohio, the state where [Registrant] is registered with DEA." *Id.* The Government requests that the Administrator revoke Registrant's DEA registration. *Id.* at 5.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on April 26, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant's

¹ The Government included a second DI Declaration, dated June 9, 2021, in its RFAA, which stated that "DEA has not received any correspondence from Spring Valley Family Pharmacy concerning the [OSC]." RFAAX 4, at 2.

right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FS7068249 at the registered address of 448 Jackson Pike, Gallipolis, OH 45631. RFAAX 1 (Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a retail pharmacy. *Id.*

The Status of Registrant's State License

On October 5, 2020, the State of Ohio Board of Pharmacy (hereinafter, Board) issued a "Settlement Agreement with the State of Ohio Board of Pharmacy" (hereinafter, Settlement Agreement). RFAAX 4, App. A. According to the Settlement Agreement, the Board had initiated an investigation of Registrant, a pharmacy licensed as a "Terminal Distributor of Dangerous Drugs," and Brandon O'Callaghan, owner and operator of Registrant, related to Mr. O'Callaghan's "illicit drug usage and failure to ensure [Registrant] [met] minimum standards and maintained sanitary compounding area conditions to ensure public safety." *Id.* at 1. The Settlement Agreement states that on or about June 19, 2019, the Board sent Registrant a Summary Suspension/ Notice of Opportunity for Hearing and that Registrant subsequently requested a hearing by and through counsel on or about July 15, 2019. *Id.* The hearing was held on or about November 5, 2019, and resulted in a Board Order that placed both Registrant's license and Mr. O'Callaghan's license on indefinite suspension subject to certain conditions. *Id.* at 2. According to the Settlement Agreement, on or about January 8, 2020, Mr. O'Callaghan violated the terms of the Order by "testing positive for amphetamine (454 ng/ml) and methamphetamine (2368 ng/ml)." *Id.* According to the Settlement Agreement, Mr. O'Callaghan subsequently surrendered his pharmacy license on May 5, 2020, and thus Registrant "no longer [had] a Responsible Person or owner that [was] lawfully allowed to possess" its license. *Id.* Under the terms of the Settlement

Agreement, Registrant permanently and voluntarily surrendered to the Board its license and registration. *Id.* at 2.

According to Ohio's online records, of which I take official notice, Registrant's state pharmacy license remains inactive.² https://elicense.ohio.gov/OH_HomePage (last visited date of signature of this Order). Accordingly, I find that Registrant is not currently licensed to dispense controlled substances in Ohio, the state in which Registrant is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term "practitioner" to mean "a pharmacy . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which [it] practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a

² Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.usdoj.gov.

practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

Under Ohio law, a terminal distributor of dangerous drugs "means a person who is engaged in the sale of dangerous drugs³ at retail . . ." and "includes pharmacies . . . and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist . . . or any other person authorized by the board of pharmacy." Ohio Rev. Code Ann. § 4729.01(Q) (West 2021). Further, Ohio law provides that, other than a licensed terminal distributor of dangerous drugs and other inapplicable exceptions, "no person shall do any of the following: (a) Sell or distribute, at retail, dangerous drugs; (b) possess for sale, at retail, dangerous drugs; (c) possess dangerous drugs." Ohio Rev. Code Ann. § 4729.51(E)(1) (West 2021).

Here, the undisputed evidence in the record is that Registrant surrendered its license as a terminal distributor of dangerous drugs in Ohio. As already discussed, a terminal distributor of dangerous drugs must be licensed to be authorized to possess or distribute controlled substances in Ohio. Thus, because Registrant permanently and voluntarily surrendered its Ohio state pharmacy license and, therefore, is not authorized to dispense controlled substances in Ohio, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

³ The definition of "dangerous drugs" includes a drug that "may be dispensed only upon a prescription" under revised code section 3719. Ohio Rev. Code Ann. § 3719.41 states that the state board of pharmacy shall adopt rules establishing the schedules of controlled substances "incorporating the five schedules of controlled substances under the federal drug abuse control laws."

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. FS7068249 issued to Spring Valley Family Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Spring Valley Family Pharmacy to renew or modify this registration, as well as any other pending application of Spring Valley Family Pharmacy for additional registration in Ohio. This Order is effective August 2, 2021.

D. Christopher Evans,
Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-829]

**Importer of Controlled Substances
Application: United States
Pharmacopeial Convention**

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: United States Pharmacopeial Convention has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

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 August 2, 2021. Such persons may also file a written request for a hearing on the application on or before August 2, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 24, 2021, United States Pharmacopeial Convention, 7135 English Muffin Way, Frederick, Maryland 21704, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Methcathinone	1237	I
Methaqualone	2565	I
Lysergic acid diethylamide	7315	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
3,4-Methylenedioxyamphetamine	7400	I
4-Methoxyamphetamine	7411	I
Codeine-N-oxide	9053	I
Difenoxin	9168	I
Heroin	9200	I
Morphine-N-oxide	9307	I
Norlevorphanol	9634	I
Methamphetamine	1105	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Phencyclidine	7471	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Phenylacetone	8501	II
Alphaprodine	9010	II
Anileridine	9020	II
Cocaine	9041	II
Dihydrocodeine	9120	II
Diphenoxylate	9170	II
Levomethorphan	9210	II
Levorphanol	9220	II
Meperidine	9230	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Sufentanil	9740	II

The company plans to import the bulk control substances for distribution as analytical reference standards to its

customers for analytical testing of raw materials.

Approval of permit applications will occur only when the registrant's business activity is consistent with what