contains a stage 7 port, P/N 2614M30P01, with a port casting serial number (S/N) listed in Table 1 in Planning Information, Paragraph 3.A., of CFM Service Bulletin (SB) LEAP–1A–72–00–0421–01A–930A–D, Issue 001, dated October 22, 2020.

**(d) Subject**

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

**(e) Unsafe Condition**

This AD was prompted by a report of a manufacturing quality escape found during inspection of an HPT case. The FAA is issuing this AD to prevent failure of the HPT case. The unsafe condition, if not addressed, could result in failure of the HPT case, uncontained rotor release, damage to the engine, and damage to the airplane.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Required Actions**

Before the HPT case exceeds the cycles since new limit in Table 1, Planning Information, Paragraph 3.A., of CFM SB LEAP–1A–72–00–0421–01A–930A–D, Issue 001, dated October 22, 2020, or during the next piece part exposure, whichever occurs first after the effective date of this AD, remove the affected HPT case from service and replace with a part eligible for installation.

**(h) Definitions**

For the purpose of this AD:

(1) A part eligible for installation is an HPT case, P/N 2668M94G01, that contains a stage 7 port, P/N 2614M30P01, with an S/N that is not listed in Table 1 in Planning Information, Paragraph 3.A., of CFM SB LEAP–1A–72–00–0421–01A–930A–D, Issue 001, dated October 22, 2020.

(2) Piece-part exposure is when the HPT case is removed from the engine and fully disassembled.

**(i) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

**(j) Related Information**

For more information about this AD, contact Christopher McGuire, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7120; fax: (781) 238–7199; email: *Chris.McGuire@faa.gov.*

**(k) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) CFM Service Bulletin LEAP–1A–72–00–0421–01A–930A–D, Issue 001, dated October 22, 2020.

(ii) [Reserved]

(3) For CFM service information identified in this AD, contact CFM International, S.A., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: (877) 432–3272; email: *aviation.fleetsupport@ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on May 21, 2021.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2021–12137 Filed 6–9–21; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**21 CFR Part 1308**
**[Docket No. DEA–715]**

### Schedules of Controlled Substances: Placement of Oliceridine in Schedule II

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts, with a change as mentioned below, an interim final rule with request for comments published in the **Federal Register** on October 30, 2020, placing oliceridine, *N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine fumarate, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible, in schedule II of the Controlled Substances Act. In response to an error in the chemical name of oliceridine as noted by one of the commenters to the interim final rule, the Drug Enforcement Administration makes a correction to the above mentioned chemical name of oliceridine by removing the word ''fumarate'' to read as *N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl}amine. This change clarifies the control of oliceridine free base and its salts, to include the fumarate salt, by definition.

**DATES:** Effective July 12, 2021.

**FOR FURTHER INFORMATION CONTACT:** Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

**SUPPLEMENTARY INFORMATION:**

#### Background and Legal Authority

On October 30, 2020, the Drug Enforcement Administration (DEA), pursuant to 21 U.S.C. 811(j), published an interim final rule (IFR) to place oliceridine (including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible), a medication approved recently by the Food and Drug Administration (FDA) for medical use as an intravenous drug for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate, in schedule II of the Controlled Substances Act (CSA). 85 FR 68749. The IFR provided an opportunity for interested persons to submit comments, as well as file a request for hearing or waiver of hearing, on or before November 30, 2020. DEA received three comments and did not receive any requests for hearing or waiver of hearing.

#### Comments Received

In response to the IFR, DEA received three comments. The submissions were from individuals or anonymous commenters. One commenter suggested that oliceridine be placed in schedule III rather than schedule II, one commenter had a statement on the controlled name, and the third commenter discussed another substance entirely that was unrelated to oliceridine. As such, the third comment was outside the scope of this current scheduling action.

*Comment:* One commenter suggested that oliceridine be placed in schedule III of the CSA, rather than schedule II. The commenter mentioned that placement of oliceridine in schedule II will limit its medical applications and limit access to the drug due to schedule II manufacturing quotas. The commenter stated that oliceridine has the potential

to revolutionize gastrointestinal endoscopy because it does not cause respiratory depression. Lastly, the commenter stated that since oliceridine is not indicated for home-use, abuse of the medication by drug users would be difficult.

*DEA Response:* DEA notes that FDA approved a New Drug Application (NDA) for oliceridine and provided DEA with a scheduling recommendation for oliceridine. The scheduling recommendation by Health and Human Services (HHS) and their notification to DEA regarding the FDA approval of the NDA initiated the DEA review and scheduling action. As stated in the IFR, after careful consideration of data from preclinical and clinical studies, DEA concurred with the HHS recommendation that oliceridine has abuse potential comparable to other schedule II opioids and therefore supported—and continues to support through this final rule—placement of oliceridine in schedule II under the CSA. Contrary to the commenter's opinion about schedule II controls on a drug limiting its medical applications and access due to manufacturing quota requirements, DEA notes that currently several schedule II drugs (oxycodone, hydrocodone etc.) are extensively prescribed and used in medical practice.

*Comment:* One commenter stated that the chemical name provided in the interim final rule indicates oliceridine is ''*N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9R)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine fumarate'', though this is the name of the fumarate salt of oliceridine. The commenter noted that the other substances listed in 21 CFR 1308.12, and in most other sections of the CSA list only the base form of the drug, and control salts by definition. The commenter suggested to provide the chemical name for oliceridine base, and the fumarate salt would be controlled under the preamble in 12 CFR 1308.12.

*DEA Response:* DEA agrees with commenter regarding the error in the chemical name of oliceridine and corrects appropriately by removing the word ''fumarate'' to read oliceridine as, *N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9R)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine. The correction will make clear precisely which substance is being controlled because the fumarate salt was not the accurate designation for the controlled substance. The listing of the base form and removal of the salt designation is consistent with other controlled substance listings under the CFR and the substance designated for control remains unchanged. The base form listing minus the salt designation (''fumarate'') is readily understood by those registered to handle the substance and would not be misunderstood by the public. For this reason, DEA believes the change will not have an impact.

Based on the rationale set forth in the interim final rule, DEA adopts the IFR, with the above mentioned correction to the chemical name of oliceridine.

**Requirements for Handling Oliceridine**

As indicated above, oliceridine has been a schedule II controlled substance by virtue of an IFR issued by DEA in October 2020. Thus, this final rule does not alter the regulatory requirements applicable to handlers of oliceridine that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Oliceridine is subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule II substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) oliceridine, or who desires to handle oliceridine, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles or intends to handle oliceridine, and is not registered with DEA, must submit an application for registration and may not continue to handle oliceridine, unless DEA has approved the application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess oliceridine pursuant to a lawful prescription.

2. *Quota.* Only registered manufacturers are permitted to manufacture oliceridine in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Any person who does not desire or is not able to maintain a schedule II registration must surrender all quantities of currently held oliceridine, or may transfer all quantities of currently held oliceridine to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

4. *Security.* Oliceridine is subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling oliceridine must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of oliceridine must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

6. *Inventory.* Every DEA registrant who possesses any quantity of oliceridine must take an inventory of oliceridine on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with DEA to handle oliceridine must take an initial inventory of all stocks of controlled substances containing oliceridine on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including oliceridine) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports for oliceridine, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Orders for oliceridine.* Every DEA registrant who distributes oliceridine is required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions.* All prescriptions for oliceridine or products containing oliceridine must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of oliceridine may only be for the

legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act, as applicable, and the CSA.

11. *Importation and Exportation.* All importation and exportation of oliceridine must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving oliceridine not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

**Regulatory Analyses**

*Administrative Procedure Act*

This final rule, with a correction in the chemical name of oliceridine as discussed above, affirms the amendment made by the IFR that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemaking. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is: (1) Approved by HHS and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause. DEA issued an IFR on October 30, 2020, and solicited public comments on that rule. Subsection (j) further provides that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). DEA is now responding to the comments submitted by the public and issuing the final rule, in conformity with the APA and the procedure required by 21 U.S.C. 811.

*Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.)12866 and the principles reaffirmed in E.O. 13563.

*Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination With Indian Tribal Governments*

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply.

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

*Congressional Review Act*

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 21 CFR part 1308, which published on October 30, 2020 (85 FR 68749), is adopted as a final rule with the following amendment:

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.12 by revising paragraph (c)(18) to read as follows:

**§ 1308.12 Schedule II.**

* * * * *

(c) * * *

(18) Oliceridine (*N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine) ..... 9245

* * * * *

**D. Christopher Evans,**

*Acting Administrator.*

[FR Doc. 2021–11981 Filed 6–9–21; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1308

**[Docket No. DEA–479]**

## Schedules of Controlled Substances: Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** By this rule, the Drug Enforcement Administration permanently places five synthetic cannabinoids, as identified in this final rule, in schedule I of the Controlled Substances Act. These five substances are currently listed in Schedule I pursuant to a temporary scheduling order. As a result of this rule, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these five specified controlled substances will continue to apply.

**DATES:** Effective June 10, 2021.

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

**SUPPLEMENTARY INFORMATION:** In this final rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following five controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible:

- naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (other names: NM2201 or CBL2201),
- *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (other name: 5F–AB-PINACA),
- 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 4-CN-CUMYL-BUTINACA, 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA, CUMYL-4CN-BINACA, or SGT-78),
- methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (other names: MMB-CHMICA or AMB-CHMICA), and
- 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (other name: 5F-CUMYL-P7AICA).

### Legal Authority

The CSA provides that issuing, amending, or repealing of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). The Attorney General initiated this action on his own motion, as delegated to the Administrator of DEA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all relevant data by DEA. The regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA will continue to apply as a result of this action.

### Background

On July 10, 2018, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (other names: NM2201 or CBL2201); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (other name: 5F-AB-PINACA); 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 4-CN-CUMYL-BUTINACA, 4-cyano-CUMYL-BUTINACA, 4-CN-CUMYL BINACA, CUMYL-4CN-BINACA or SGT-78); methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (other names: MMB-CHMICA or AMB-CHMICA) and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (other name: 5F-CUMYL-P7AICA) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 31877. That temporary scheduling order took effect on the date of publication, and was based on findings by the former Acting Administrator of DEA that the temporary scheduling of these five synthetic cannabinoids (SCs) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

On July 13, 2020, DEA published an order to extend the temporary scheduling of the five SCs by one year, until July 10, 2021. 85 FR 42296. Also, on that same date and in the same issue of the **Federal Register**, DEA published a notice of proposed rulemaking (NPRM) to permanently control the five SCs in schedule I of the CSA. 85 FR 42290. Specifically, DEA proposed to add these five SCs to the hallucinogenic substances list under 21 CFR 1308.11(d).

### DEA and HHS Eight Factor Analyses

On May 29, 2020, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), entitled ''Basis for the Recommendation to Place Naphthalen-1-yl 1-(5-fluoropentyl)-lH-indole-3-carboxylate [NM2201; CBL2201], N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-lH-indazole-3-carboxamide [5F-AB-PINACA], 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)lH-indazole-3-carboxamide (4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78], methyl 2-(1-(cyclohexylmethyl)-lH-indole-3-carboxamido)-3-methylbutanoate [MMB-CHMICA; AMB-CHMICA], and 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide [5F-CUMYL-P7AICA; CUMYL-5F-P7AICA; SGT-263] and Their Salts in Schedule I of the Controlled Substances Act.''

After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C.

[1] As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.