

**§ 880.6305 Ingestible event marker.**

(a) *Identification.* An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible and non-toxic;

(2) Nonclinical, animal, and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;

(3) Appropriate analysis and nonclinical testing must validate electromagnetic compatibility performance, wireless performance, and electrical safety; and

(4) Labeling must include a detailed summary of the nonclinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

Dated: May 10, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA–373]

**Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cannabinoids Into Schedule I**

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

**ACTION:** Final order.

**SUMMARY:** The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule three synthetic cannabinoids under the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-

fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids and their salts, isomers and salts of isomers into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the full effect of the CSA and the Controlled Substances Import and Export Act (CSIEA) and their implementing regulations including criminal, civil and administrative penalties, sanctions and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

**DATES:** *Effective Date:* This Final Order is effective on May 16, 2013.

**FOR FURTHER INFORMATION CONTACT:** John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; telephone (202) 307–7165.

**SUPPLEMENTARY INFORMATION:****Background**

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling up to one year.

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355) for the substance (21 U.S.C. 811(h)(1)). The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA, who in turn has delegated her authority to the Deputy Administrator of DEA. 28 CFR 0.100, Appendix to Subpart R.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into

Schedule I of the CSA.<sup>1</sup> The Deputy Administrator has transmitted notice of his intent to place UR-144, XLR11 and AKB48 in Schedule I on a temporary basis to the Assistant Secretary by letter dated February 14, 2013. The Assistant Secretary responded to this notice by letter dated March 14, 2013 (received by DEA on March 21, 2013), and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for UR-144, XLR11 or AKB48. The Assistant Secretary also stated that HHS has no objection to the temporary placement of UR-144, XLR11 or AKB48 into Schedule I of the CSA. DEA has taken into consideration the Assistant Secretary's comments (21 U.S.C. 811(h)(4)). As UR-144, XLR11 and AKB48 are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for UR-144, XLR11 and AKB48 under Section 505 of the FD&C Act (21 U.S.C. 355), DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. On April 12, 2013, a Notice of Intent to temporarily schedule these three synthetic cannabinoids was published in the **Federal Register** (78 FR 21858).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(h)(3)). These factors are as follows: the substance's history and current pattern of abuse; the scope, duration and significance of abuse, and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)–(6). Consideration of these factors includes actual abuse, diversion from legitimate channels and clandestine importation, manufacture or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)) may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for

<sup>1</sup> Because the Secretary of the Department of Health and Human Services (HHS) has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, 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 Controlled Substance Act (CSA), with the concurrence of NIDA. 50 FR 9518.

abuse, no currently accepted medical use in treatment in the United States (U.S.), and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for UR-144, XLR11 and AKB48 indicate that these three synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision.

### Synthetic Cannabinoids

While synthetic cannabinoids have been developed over the last 30 years for research purposes to investigate the cannabinoid system, no scientific literature referring to UR-144, XLR11 or AKB48 was available prior to these drugs' identification in the illicit market. In addition, no legitimate non-research uses have been identified for these synthetic cannabinoids nor have they been approved by FDA for human consumption. Synthetic cannabinoids, of which (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) are representative, are so-termed for their Δ9-tetrahydrocannabinol (THC)-like pharmacological properties. Numerous herbal products have been analyzed, and UR-144, XLR11 and AKB48 have been identified, in varying mixture profiles and amounts, spiked on plant material.

As of April 3, 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE) data, there are 1,510 reports involving 179 total cases for UR-144, 1,194 reports involving 186 total cases for XLR11 and 112 reports involving 40 total cases for AKB48. From January 2010 to March 2013, the National Forensic Laboratory Information System (NFLIS) registered 14,831 reports containing these synthetic cannabinoids (UR-144—5,465 reports; XLR11—8,837 reports; AKB48—529 reports) from at least 32 states. No instances regarding UR-144, XLR11 or AKB48 were reported in NFLIS prior to March of 2010. For the period January 2010 through March 2013, NFLIS and STRIDE reports<sup>2</sup> for

the three synthetic cannabinoids UR-144, XLR11 and AKB48 (16,014 total reports) exceeded the number of reports for the five synthetic cannabinoids JWH-018, JWH-073, JWH-200, CP-47,497 and CP-47,497 C8 (7,555 total reports). JWH-018, JWH-200, JWH-073, CP-47,497 and CP-47,497 C8 homologue were temporarily scheduled on March 1, 2011, and later placed in Schedule I by Section 1152 of Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112-144, on July 9, 2012. Section 1152 of the FDASIA<sup>3</sup> amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 phenethylamines of the 2C-series) in Schedule I. UR-144, XLR11 and AKB48 were not included among the 15 specific named synthetic cannabinoids, and do not fall under the definition of cannabimimetic agents, under FDASIA.

### Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids (JWH-018) laced on plant material were first reported in the U.S. in December 2008, when a shipment of "Spice" was seized and analyzed by U.S. Customs and Border Patrol in Dayton, Ohio. Also in December 2008, JWH-018 and cannabicyclohexanol were identified by German forensic laboratories.

Since the initial identification of JWH-018 (December 2008), many additional synthetic cannabinoids with purported psychotropic effects have been found laced on plant material or related products. The popularity of these synthetic cannabinoids and their associated products appears to have increased since January 2010 in the U.S. based on seizure exhibits and media reports. This trend appears to mirror that experienced in Europe since 2008. Synthetic cannabinoids are being encountered in several regions of the U.S. with the substances primarily found as adulterants on plant material products as self-reported on internet discussion boards. Since then, numerous other synthetic cannabinoids including UR-144, XLR11 and AKB48 have been identified as product adulterants.

Data gathered from published studies, supplemented by discussions on Internet Web sites and personal communications with toxicological

testing laboratories, demonstrate that products laced with UR-144, XLR11 and/or AKB48 are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as 'legal' alternatives to marijuana. This characterization, along with their reputation as potent herbal intoxicants, has increased their popularity. Several synthetic cannabinoids, including UR-144, XLR11 and AKB48, have been shown to display higher potency in scientific studies when compared to THC. Smoking mixtures of these substances for the purpose of achieving intoxication has been identified as a reason for numerous emergency room visits and calls to poison control centers. Abuse of these synthetic cannabinoids and their products has been characterized with both acute and long term public health and safety issues. In addition, numerous states, local jurisdictions, and the international community have controlled these substances.

### Factor 5. Scope, Duration and Significance of Abuse

According to forensic laboratory reports, the first appearance of synthetic cannabinoids in the U.S. occurred in December 2008, when U.S. Customs and Border Protection analyzed "Spice" products. NFLIS has reported 14,831 exhibits (January 2010 to March 2013) related to UR-144, XLR11 and AKB48 from various states including Alaska, Alabama, Arkansas, California, Colorado, Florida, Georgia, Iowa, Indiana, Illinois, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, North Dakota, Nebraska, Nevada, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming. STRIDE has reported 2,816 records involving UR-144, XLR11 and/or AKB48 from January 2010 through April 3, 2013. From January 1 through December 31, 2012, the American Association of Poison Control Centers<sup>4</sup> has reported receiving in excess of 5,200 calls relating to products purportedly laced with synthetic cannabinoids. Although the center does not identify specific cannabinoid substances, the data does indicate the magnitude of adverse exposure to synthetic cannabinoids.

### Factor 6. What, If Any, Risk There Is to the Public Health

UR-144, XLR11 and AKB48 are pharmacologically similar to Schedule I

<sup>2</sup> National Forensic Laboratory Information System (NFLIS) is a program sponsored by the Drug Enforcement Administration's (DEA), Office of Diversion Control which compiles information on exhibits analyzed in State and local law enforcement forensic laboratories. System to Retrieve Information from Drug Evidence (STRIDE)

is a DEA database which compiles information on exhibits analyzed in DEA laboratories.

<sup>3</sup> Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (FDASIA), which includes Sections 1151-1153 of Pub. L. 112-144, is also known as the "Synthetic Drug Abuse Prevention Act of 2012," or "SDAPA."

<sup>4</sup> American Association of Poison Control Centers (AAPCC) is a non-profit, national organization that represents the poison centers of the United States.

substances THC and JWH-018, as well as other synthetic cannabinoids. By sharing pharmacological similarities with the Schedule I substances (THC and JWH-018), synthetic cannabinoids pose a risk to the abuser. In addition, the chronic abuse of products laced with synthetic cannabinoids has also been linked to addiction and withdrawal. Law enforcement, military and public health officials have reported exposure incidents that demonstrate the dangers associated with abuse of synthetic cannabinoids to both the individual abusers and other affected individuals since these substances were never intended for human use. Warnings regarding the dangers associated with abuse of synthetic cannabinoids and their products have been issued by numerous state public health departments, poison control centers and private organizations. In a 2012 report, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported 11,406 emergency department visits involving a synthetic cannabinoid product during 2010. In a 2013 report, SAMHSA reported the number of emergency department visits in 2011 involving a synthetic cannabinoid product had increased 2.5 times to 28,531.

Detailed product analyses have detected variations in the amount and type of synthetic cannabinoid laced on plant material even within samplings of the same product. Since abusers obtain these drugs through unknown sources, purity of these drugs is uncertain, thus posing significant adverse health risk to these users. Submissions to DEA laboratories from January 2012 through February 11, 2013, have documented over 142 distinct packaging examples containing a mixture of UR-144, XLR11 and/or AKB48. These unknown factors present a significant risk of danger to the abuser. Some of the adverse health effects reported in response to the abuse of synthetic cannabinoids include vomiting, anxiety, agitation, irritability, seizures, hallucinations, tachycardia, elevated blood pressure, and loss of consciousness. As mentioned above, there are reported instances of emergency department admissions in association with the abuse of these THC-like substances. There are no recognized therapeutic uses of these substances in the U.S.

In February 2013, the Centers for Disease Control and Prevention published a report by Murphy et al. describing unexplained cases of acute kidney injury in 16 patients, all of whom had reported recent smoking of synthetic cannabinoids. Upon further investigation, it was determined that of

the 16 patients, 7 of the subjects had smoked substances that were positive for XLR11 or its metabolite. Cases were reported from Wyoming (4 cases), Rhode Island (1 case), New York (2 cases), Oregon (6 cases), Kansas (1 case) and Oklahoma (2 cases).

#### **Finding of Necessity of Schedule I Scheduling To Avoid Imminent Hazard to Public Safety**

Based on the available data and information, the continued uncontrolled manufacture, distribution, importation, exportation and abuse of UR-144, XLR11 and AKB48 pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for these synthetic cannabinoids in the U.S. A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)) may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision. Available data and information for UR-144, XLR11 and AKB48 indicate that these three synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision.

#### **Conclusion**

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)), the Deputy Administrator has considered available data and information and has set forth herein the grounds for his determination that it is necessary to temporarily schedule three synthetic cannabinoids, (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) in Schedule I of the CSA and finds that placement of these synthetic cannabinoids into Schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into Schedule I to avoid an imminent hazard to the public safety, the final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of up to three years pending

completion of the permanent or regular scheduling process.

Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth specific criteria for scheduling a drug or other substance. While temporary scheduling orders are not subject to judicial review (21 U.S.C. 811(h)(6)), the regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a permanent scheduling determination. Final decisions which conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877.

#### **Regulatory Requirements**

With the issuance of this final order, UR-144, XLR11 and AKB48 become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importation and exportation of a Schedule I controlled substance under the CSA and the CSIEA.

1. Registration. Any person who manufactures, distributes, imports, exports, or possesses UR-144, XLR11 or AKB48, or who engages in research or conducts instructional activities with respect to UR-144, XLR11 or AKB48, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with 21 U.S.C. 822 and 957. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration and may not continue their activities until DEA has approved that application. Retail sales of Schedule I controlled substances to the general public are not allowed under the CSA. Possession of any of these substances in a manner not authorized by the CSA on or after May 16, 2013 is unlawful and may subject those in possession of any of these substances to prosecution pursuant to the Controlled Substances Act.

2. Security. UR-144, XLR11 and AKB48 are subject to Schedule I security requirements. Accordingly, appropriately registered DEA registrants must manufacture, distribute and store these substances in accordance with 1301.71; 1301.72(a), (c) and (d); 1301.73; 1301.74; 1301.75(a) and (c); and 1301.76 of Title 21 of the Code of Federal Regulations as of May 16, 2013.

3. Labeling and packaging. All labeling and packaging requirements for controlled substances set forth in Part 1302 of Title 21 of the Code of Federal Regulations shall apply to commercial containers of UR-144, XLR11 and AKB48. Current DEA registrants authorized to handle UR-144, XLR11 and AKB48 shall comply with Part 1302 of Title 21 of the Code of Federal Regulations within thirty (30) calendar days of May 16, 2013.

4. Quotas. Every manufacturer authorized to manufacture UR-144, XLR11 and AKB48 must apply for and be granted a quota to manufacture such substance(s) pursuant to Part 1303 of Title 21 of the Code of Federal Regulations. No authorized manufacturer may manufacture UR-144, XLR11 or AKB48 in excess of a quota assigned to him as of May 16, 2013.

5. Inventory. Every DEA registrant authorized to possess any quantity of UR-144, XLR11 or AKB48 is required to keep inventory of all stocks of these substances on hand pursuant to 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every authorized DEA registrant shall comply with all inventory requirements within thirty (30) calendar days of May 16, 2013.

6. Records. All registrants who are authorized to handle UR-144, XLR11 or AKB48 are required to keep records pursuant to 1304.03, 1304.04, 1304.21, 1304.22 and 1304.23 of Title 21 of the Code of Federal Regulations. Current DEA registrants authorized to handle UR-144, XLR11 or AKB48 shall comply with all recordkeeping requirements within thirty (30) calendar days of May 16, 2013.

7. Reports. All registrants are required to submit reports in accordance with 1304.33 of Title 21 of the Code of Federal Regulations. Registrants who manufacture or distribute UR-144, XLR11 or AKB48 are required to comply with these reporting requirements and shall do so as of May 16, 2013.

8. Order Forms. All registrants involved in the distribution of UR-144, XLR11 or AKB48 must comply with order form requirements of Part 1305 of Title 21 of the Code of Federal Regulations as of May 16, 2013.

9. Importation and Exportation. All importation and exportation of UR-144, XLR11 or AKB48 must be conducted by appropriately registered DEA registrants in compliance with Part 1312 of Title 21 of the Code of Federal Regulations on or after May 16, 2013.

10. Criminal Liability. The manufacture, distribution or possession with the intent to conduct these activities; as well as possession,

importation or exportation of UR-144, XLR11 or AKB48 not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act occurring as of May 16, 2013 is unlawful.

### Regulatory Matters

Section 201(h) of the CSA (21 U.S.C. 811(h)) provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of a proposed temporary scheduling order is transmitted to the Secretary of HHS. 21 U.S.C. 811(h)(1).

In as much as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) do not apply to this final order. In the alternative, even assuming that this final order might be deemed to be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency of the temporary scheduling action to avoid an imminent hazard to the public safety.

Further, DEA believes that this temporary scheduling action Final Order is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where (as here) the agency is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 "Regulatory Planning and Review," section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 "Federalism" it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801–808), DEA has submitted a copy of this Final Order 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.

Under the authority vested in the Attorney General by section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations (28 CFR 0.100, Appendix to Subpart R), the Deputy Administrator hereby orders that 21 CFR part 1308 be amended as follows:

### 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), unless otherwise noted.

■ 2. Section 1308.11 is amended by adding new paragraphs (h)(9), (10), and (11) to read as follows:

#### § 1308.11 Schedule I.

\* \* \* \* \*

(h) \* \* \*

(9) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers—7144 (Other names: UR-144, 1-pentyl-3-(2,2,3,3-tetramethylcyclopropoyl)indole)

(10) [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers—7011 (Other names: 5-fluoro-UR-144, 5-F-UR-144, XLR11, 1-(5-fluoro-pentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole)

(11) *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7048 (Other names: APINACA, AKB48)

Dated: May 10, 2013.

**Thomas M. Harrigan,**  
*Deputy Administrator.*

[FR Doc. 2013-11593 Filed 5-15-13; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Part 5

[Docket No. TTB-2012-0001; T.D. TTB-113;  
Re: Notice No. 126]

RIN 1513-AB91

#### Standards of Identity for Pisco and Cognac

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** This final rule amends the Alcohol and Tobacco Tax and Trade Bureau regulations setting forth the standards of identity for distilled spirits to include Pisco as a type of brandy that must be manufactured in accordance with the laws and regulations of either Peru or Chile, as appropriate, governing the manufacture of those products. This final rule also removes “Pisco brandy” from the list of examples of geographical designations in the distilled spirits standards of identity, and it includes a technical correction to remove “Cognac” from the same list of examples. These changes provide greater clarity in distilled spirits labeling.

**DATES:** *Effective Date:* This final rule is effective July 15, 2013.

**FOR FURTHER INFORMATION CONTACT:** Karen Welch, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Rulings Division; telephone 202-453-1039, ext. 046; email [ITD@ttb.gov](mailto:ITD@ttb.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

##### TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified in the United States Code at 27 U.S.C. 205(e), authorizes the Secretary of the Treasury (Secretary) to prescribe regulations relating to the packaging, marking, branding, labeling, and size and fill of containers of alcohol beverages that will prohibit consumer deception and provide the consumer with adequate information as to the identity and quality of the product. Section 105(e) of the FAA Act also generally requires bottlers and importers

of alcohol beverages to obtain certificates of label approval prior to bottling or importing alcohol beverages for sale in interstate commerce. Regulations implementing those provisions of section 105(e) as they relate to distilled spirits are set forth in part 5 of title 27 of the Code of Federal Regulations (27 CFR part 5). The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

##### *Certificates of Label Approval*

TTB's regulations prohibit the release of bottled distilled spirits from customs custody for consumption unless an approved Certificate of Label Approval (COLA) covering the product has been deposited with the appropriate Customs officer at the port of entry. See 27 CFR 5.51. The TTB regulations also generally prohibit the bottling or removal from a plant of distilled spirits unless the proprietor possesses a COLA covering the labels on the bottle. See 27 CFR 5.55.

##### *Classes and Types of Spirits*

The TTB labeling regulations require that the class and type of distilled spirits appear on the product's brand label. See 27 CFR 5.32(a)(2) and 5.35. Those regulations provide that the class and type must be stated in conformity with § 5.22 of the TTB regulations (27 CFR 5.22) if defined therein. Otherwise, the product must be designated in accordance with trade and consumer understanding thereof, or, if no such understanding exists, by a distinctive or fanciful name, and in either case (with limited exceptions), followed by a truthful and adequate statement of composition (see 27 CFR 5.35).

Section 5.22 establishes standards of identity for distilled spirits products and categorizes these products according to various classes and types. As used in § 5.22, the term “class” refers to a general category of spirits, such as “whisky” or “brandy.” Currently, there are 12 different classes of distilled spirits recognized in § 5.22, including whisky, rum, and brandy. The term “type” refers to a subcategory within a class of spirits. For example, “Cognac” is a type of brandy, and “Canadian whisky” is a type of whisky.

##### *Brandy and Pisco*

Brandy is Class 4 in the standards of identity, where it is defined in § 5.22(d) as “an alcoholic distillate from the fermented juice, mash, or wine of fruit, or from the residue thereof, produced at less than 190° proof in such manner that the distillate possesses the taste, aroma, and characteristics generally attributed to the product, and bottled at not less than 80° proof.” “Pisco” is a term recognized by both the governments of Peru and Chile as a designation for a distilled spirits product made from grapes. Generally, Pisco is classified as brandy under the terms of TTB's current labeling regulations. However, Pisco is not currently listed as a type of brandy in Class 4. Rather, “Pisco brandy” has been included in Class 11, at § 5.22(k)(3), as an example of a geographical name that is not a name for a distinctive type of distilled spirits, and that has not become generic.

##### International Agreements

Pursuant to the United States-Peru Trade Promotion Agreement, the United States recognized Pisco Perú as a distinctive product of Peru (Article 2.12(2) of the Agreement). Accordingly, the United States agreed not to permit the sale of any product as Pisco Perú unless it has been manufactured in Peru in accordance with the laws and regulations of Peru governing Pisco.

In addition, pursuant to the United States-Chile Free Trade Agreement, the United States recognized Pisco Chileno (Chilean Pisco) as a distinctive product of Chile (Article 3.15(2) of the Agreement). Accordingly, the United States agreed not to permit the sale of any product as Pisco Chileno (Chilean Pisco) unless it has been manufactured in Chile in accordance with the laws and regulations of Chile governing the manufacture of Pisco.

In like manner, Peru and Chile agreed, respectively, to recognize Bourbon Whiskey and Tennessee Whiskey (which is defined in both Agreements as a straight Bourbon Whiskey authorized to be produced only in the State of Tennessee), as distinctive products of the United States, and not to permit the sale of any product as Bourbon Whiskey or Tennessee Whiskey unless it has been manufactured in the United States in accordance with the laws and regulations of the United States governing the manufacture of Bourbon Whiskey and Tennessee Whiskey. (TTB notes that there are alternative spellings for the same term—“whisky” in the TTB regulations in 27 CFR part 5 and “whiskey” in the Agreements with Peru and Chile.)