

Phenol (less than 1.5 percent)
 Poloxamer iodine complex
 Povidone-iodine (5 to 10 percent)
 Secondary amyltricresols
 Sodium oxychlorosene
 Tribromsalan
 Triclocarban
 Triclosan
 Triple Dye
 Undecoylium chloride iodine complex

* * * * *

(d) * * *

(41) September 6, 2017, for products subject to paragraph (a)(27)(iii) or (iv) of this section.

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-21337 Filed 9-2-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-433]

Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA and ADB-PINACA into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical

analysis, or possess), or propose to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

DATES: *Effective date:* September 6, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. 21 U.S.C. 801-971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.” The Attorney General has

delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her 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). This action was initiated by the former Deputy Administrator of the DEA on his own motion and is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA.

Background

On January 10, 2014, the DEA published a notice of intent to temporarily place quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) into schedule I pursuant to the temporary scheduling provisions of the CSA. 79 FR 1776. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA. 79 FR 7577. That final order was effective on the date of publication, and was based on findings by the DEA that the temporary scheduling of these four synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

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), the FDA acts as the lead agency within the 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 the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.”

Section 201(h)(2) of the CSA requires that the temporary control of these substances expires two years from the effective date of the scheduling order, or on or before February 9, 2016. 21 U.S.C. 811(h)(2). However, the CSA also provides that the temporary scheduling may be extended for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1). *Id.*

Accordingly, on February 5, 2016, the DEA extended the temporary scheduling of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA by one year, until February 9, 2017. 81 FR 6175. Also, on February 5, 2016, DEA published a notice of proposed rulemaking (NPRM) to permanently control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA. 81 FR 6190.

DEA and HHS Eight Factor Analyses

On January 19, 2016, the HHS provided the DEA with four scientific and medical evaluation documents prepared by the FDA entitled “Basis for the recommendation to place 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester or quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” “Basis for the recommendation to place quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5F-PB-22) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” “Basis for the recommendation to place N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” and “Basis for the recommendation to place N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA).” After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA and concluded that these substances warrant control in schedule I of the CSA. Both the DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–433/DEA–2016–0002) at <http://www.regulations.gov> under “Supporting Documents.”

Determination To Schedule PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

After a review of the available data, including the scientific and medical evaluations and the scheduling recommendations from the HHS, the DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA into Schedule I,” proposing to control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA. 81 FR 6190. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before March 7, 2016. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before March 7, 2016.

Comments Received

The DEA received three comments on the proposed rule to control PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA in schedule I of the CSA.

1. *Request for Alternate Manufacturing/Packaging of Opiate Pills:* One commenter stated that alternate manufacturing and packaging of opiate pills would reduce access to these drugs. The comment was addressed to the FDA.

- *DEA Response:* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are synthetic cannabinoid substances. Opiate pills are not addressed or affected by this rulemaking.

2. *Support for rulemaking:* One commenter gave support for the rulemaking stating that the rule was a step in the right direction.

- *DEA Response:* The DEA appreciates the comment in support of this rulemaking.

3. *Mixed Support and Dissent:* One commenter supported in part and dissented in part, suggesting that research into potential medical uses of these substances be conducted prior to scheduling.

- *DEA Response:* On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA. 79 FR 7577. That final order was based on findings by the DEA that the temporary scheduling of these four synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Adverse effects following ingestion of these substances have included:

Seizures, neurotoxicity, and death for PB-22; respiratory failure, organ failure, and death for 5F-PB-22; diaphoresis, nausea, confusion, tachycardia, and death for AB-FUBINACA; and anxiety, delirium, psychosis, aggression, and seizures for ADB-PINACA. There is no currently accepted medical use for these four substances in treatment in the United States, and the substances fulfill all requirements for placement into schedule I of the CSA.

After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA be controlled in schedule I of the CSA. In response, the DEA reviewed the scientific and medical evaluations of HHS and all other relevant data on PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA and concurs with the HHS evaluations and findings. The current scientific, medical and other evidence on PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA warrant control of these substances in schedule I of the CSA.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluations and accompanying recommendations of the HHS, and the DEA’s consideration of its own eight-factor analyses, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. As such, the DEA is scheduling PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analyses and recommendations of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) and N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-

pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9 -THC) and JWH-018;

(2) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) under medical supervision.

Based on these findings, the Administrator of the DEA concludes that quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC), quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) including their salts, isomers and salts of isomers, including optical, positional and geometric isomers, whenever the existence of such salts, isomers, salts of isomers, optical isomers, positional isomers, and geometric isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA

Upon the effective date of this final rule, any person who handles PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA continues² to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research and conduct of instructional activities or chemical

analysis, and possession of schedule I controlled substances, including those listed below. These controls will continue on a permanent basis:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA, or who desires to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must be registered with the 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 as of September 6, 2016. Any person who currently handles PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA and is not registered with the DEA must submit an application for registration and may not continue to handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA as of September 6, 2016 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of Stocks.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA continue to be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.93 as of September 6, 2016.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA must continue to comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302 as of September 6, 2016.

5. *Quota.* Only registered manufacturers are permitted to manufacture PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of September 6, 2016.

6. *Inventory.* Every DEA registrant whose registration currently authorizes handling of these substances and who possesses any quantity of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on the effective date of this final rule is required to continue to maintain an inventory of all stocks of PB-22, 5F-PB-22, AB-FUBINACA, and/or

ADB-PINACA on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA on or after the effective date of the final rule is required to take an initial inventory of all stocks of PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA on hand pursuant to 21 U.S.C. 827 and 958, 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 PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317 as of September 6, 2016. Manufacturers and distributors must submit reports regarding PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of September 6, 2016.

8. *Order Forms.* Every DEA registrant who distributes PB-22, 5F-PB-22, AB-FUBINACA, and/or ADB-PINACA must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305, as of September 6, 2016.

9. *Importation and Exportation.* All importation and exportation of PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of September 6, 2016.

10. *Liability.* Any activity involving PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA not authorized by, or in violation of, the CSA or its implementing regulations continues to be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a

² PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 81 FR 6175, Feb. 5, 2016.

hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the 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 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 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 Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or 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 Executive Order 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 Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 7577. On February 5, 2016, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 81 FR 6175. Accordingly, all entities that currently handle or plan to handle these synthetic cannabinoids are

estimated to have already established and implemented the systems and processes required to handle PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on businesses that currently handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA for lawful purposes. This estimate applies to entities large and small. Accordingly, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action will 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 \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would 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 section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: “an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted 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.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. Amend § 1308.11 as follows:

■ a. Add paragraphs (d)(51) through (54);

■ b. Remove paragraphs (h)(4) through (7);

■ c. Redesignate paragraphs (h)(8) through (22) as paragraphs (h)(4) through (18); and

■ d. Redesignate paragraphs (h)(26) and (27) as paragraphs (h)(19) and (20).

The additions read as follows:

§ 1308.11 Schedule I.

*	*	*	*	*
(d)	*	*	*	
(51)	quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC)	(7222)		
(52)	quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	(7225)		
(53)	<i>N</i> -(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamide (AB-FUBINACA)	(7012)		
(54)	<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (ADB-PINACA)	(7035)		
*	*	*	*	*

Dated: August 30, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–21345 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0241]

RIN 1625–AA00

Safety Zone; Swim Around Charleston; Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.