§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 2007 Canadian Area Navigation Routes.

* * * * *

Q–917 Sault Ste Marie, MI (SSM) to WOZEE, NY [Amended]

Sault Ste Marie, MI (SSM)	VOR/DME	(Lat. 46°24′43.60″ N., long. 084°18′53.54″ W.)
ULUTO, Canada	WP	(Lat. 46°18′16.00″ N., long. 084°05′41.00″ W.)
VIGLO, Canada	WP	(Lat. 45°23′48.00″ N., long. 082°25′11.00″ W.)
DUTEL, Canada	WP	(Lat. 44°39′59.00″ N., long. 081°17′47.00″ W.)
PEPLA, Canada	WP	(Lat. 43°47′50.98″ N., long. 080°00′53.56″ W.)
HOZIR, NY	WP	(Lat. 43°06′03.59″ N., long. 079°02′05.27″ W.)
WOZEE, NY	WP	(Lat. 42°56′01.65″ N., long. 078°44′19.64″ W.)

Excluding the airspace within Canada.

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Q–923 HOCKE, MI to DUTEL, Canada [Amended]

HOCKE, MI	WP	(Lat. 43°15′43.38″ N., long. 082°42′38.27″ W.)
KARIT, MI	WP	(Lat. 43°43′23.00″ N., long. 082°08′40.00″ W.)
DUTEL, Canada	WP	(Lat. 44°39′59.00″ N., long. 081°17′47.00″ W.)

Excluding the airspace within Canada.

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Issued in Washington, DC, on March 1, 2017.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2017–04568 Filed 3–8–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–435]

Schedules of Controlled Substances: Placement of Brivaracetam Into Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts without change an interim final rule with request for comments published in the **Federal Register** on May 12, 2016. The Drug Enforcement Administration is placing the substance brivaracetam ((2*S*)-2-[(4*R*)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB–34714; Briviact) (including its salts) into schedule V of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act, as revised by the Improving Regulatory Transparency for New Medical Therapies Act which was signed into law on November 25, 2015.

DATES: The effective date of this final rulemaking is March 9, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette 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 purpose of this action. 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 providing 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, controlled substances are classified into one of five schedules based upon their potential for abuse, their 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 all scheduled substances is published at 21 CFR part 1308.

The Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89) was signed into law on November 25, 2015. This law amended the CSA and states that in cases where the DEA receives notification from HHS that the Secretary has approved an application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), the DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug not later than 90 days after receiving such notification from HHS and subsequently to issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to section 811(j), the DEA must apply the scheduling criteria of subsections 811(b), (c), and (d) and section 812(b). 21 U.S.C. 811(j)(3).

Background

Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide)

(also referred to as BRV; UCB–34714; Briviact) is a new molecular entity with central nervous system (CNS) depressant properties. BRV is known to be a high affinity ligand for the synaptic vesicle protein, SV2A, which is found on excitatory synapses in the brain. On November 22, 2014, UCB Inc. (Sponsor) submitted three New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for the tablet, oral, and intravenous formulations of BRV. The FDA accepted the NDA filings for BRV on January 21, 2015.

On March 28, 2016 the DEA received notification that the HHS/FDA approved BRV, under section 505(c) of the FDCA, as an add-on treatment to other medications to treat partial onset seizures in patients age 16 years and older with epilepsy.

On May 12, 2016, the DEA published an interim final rule [81 FR 29487] to make BRV (including its salts) a schedule V controlled substance(s). Interested persons were provided a 30 day comment period in which to file written comments on this rulemaking in accordance with 21 CFR 1308.43(g). In addition, interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' were provided an opportunity to file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44. The deadline for submitting comments or requests for hearing/waiver of hearing was June 13, 2016.

In response to the interim final rule, the DEA did not receive any comments. In addition, the DEA did not receive any requests for hearing or waiver of hearing pursuant to 21 CFR 1308.44. Based on the rationale set forth in the interim final rule, the DEA adopts the interim final rule, without change.

Requirements for Handling Brivaracetam

BRV is subject to the CSA's schedule V 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 V 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) BRV, or who desires to handle BRV, 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. Any person who currently handles BRV, and is not registered with the DEA, must submit an application for registration and may not continue to handle BRV, unless the DEA has approved that application for registration, 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.* Any person who does not desire or is not able to obtain a schedule V registration must surrender all quantities of currently held BRV, or may transfer all quantities of currently held BRV to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* BRV is subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71–1301.93.

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

5. *Inventory.* Every DEA registrant who possesses any quantity of BRV must take an inventory of BRV 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 must take an initial inventory of all stocks of controlled substances (including BRV) on hand on the date the registrant first engages in the handling of controlled substances, 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 BRV) 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.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports for BRV, or products containing BRV, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

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

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

9. *Liability.* Any activity involving BRV 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, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA shall issue an interim final rule scheduling the drug within 90 days. This action was taken May 12, 2016. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause.

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

In accordance with Public Law 114–89, 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 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 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 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 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. As noted in the above discussion regarding applicability of the Administrative Procedure Act, the DEA was not required to publish a general notice of proposed rulemaking prior to this final rule. 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.,* the DEA has determined and certifies 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 $100,000,000 or more (adjusted for inflation) in any one year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under 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 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.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim final rule amending 21 CFR part 1308, which published on May 12, 2016 (81 FR 29487), is adopted as a final rule without change.

Dated: February 22, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–04698 Filed 3–8–17; 8:45 am]

BILLING CODE 4410–09–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 74

[MB Docket No. 13–249; FCC 17–14]

Revitalization of the AM Radio Service

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Commission's rule setting forth the allowable location of an FM translator station rebroadcasting the signal of an AM broadcast station. It changes the rule so that an AM broadcaster has a greater area in which an FM translator rebroadcasting the AM signal may be located, giving AM broadcasters greater flexibility in reaching their listeners. The change is necessary to accommodate AM radio stations located far from their communities of license, or those with highly directional signal patterns.

DATES: This rule is effective April 10, 2017. The effective date is delayed indefinitely pending Office of Management and Budget (OMB) approval of a non-substantive change to the rule as originally proposed. The Commission will publish a document in the **Federal Register** announcing the effective date.

FOR FURTHER INFORMATION CONTACT: Peter Doyle, Chief, Media Bureau, Audio Division, (202) 418–2700 or *Peter.Doyle@fcc.gov;* Thomas Nessinger, Senior Counsel, Media Bureau, Audio Division, (202) 418–2700 or *Thomas.Nessinger@fcc.gov.*

For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Cathy Williams at 202–418–2918, or via the Internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order (Second R&O), FCC 17–14, adopted February 23, 2017, and released February 24, 2017. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, 445 Twelfth Street SW., Room CY–A257, Portals II, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Paperwork Reduction Act of 1995 Analysis

This Second R&O adopts new or revised information collection requirements, subject to the Paperwork Reduction Act of 1995 (PRA) (Pub. L. 104–13, 109 Stat 163 (1995) (codified in 44 U.S.C. 3501–3520)). The Office of Management and Budget (OMB) preapproved the information collection requirements, as set forth in the *Further Notice of Proposed Rulemaking* (FNPRM) in this proceeding, 81 FR 2818, January 19, 2016, as follows: FCC Form 345, under OMB control number 3060–0075, on March 17, 2016; and FCC Form 349, under OMB control number 3060–0405, on March 21, 2016. The Commission will receive OMB's final approval for the information collection requirements by submitting a non-substantive change submission to OMB for review under section 3507(d) of the PRA (44 U.S.C. 3507(d)).

In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might ''further reduce the information collection burden for small