■ c. Removing the comma at the end of paragraph (b)(5)(i) and adding a semicolon in its place;
■ d. Revising paragraphs (c) and (e) introductory text;
■ e. Removing the commas at the ends of paragraphs (e)(1) and (2) and adding semicolons in their place; and
■ f. Revising paragraphs (f) and (h)(1) and (2).

The revisions read as follows:

§ 814.20 Application.

* * * * *

(b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include in electronic format:

* * * * *

(2) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on nonclinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted as a single version. The applicant shall include information that it believes to be trade secret or confidential commercial or financial information in the PMA and identify the information that it believes to be trade secret or confidential commercial or financial information.

* * * * *

(c) Pertinent information in FDA files specifically referred to by an applicant may be incorporated into a PMA by reference. Information in a master file or other information submitted to FDA by a person other than the applicant will not be considered part of a PMA unless such reference is authorized in a record submitted to FDA by the person who submitted the information or the master file. If a master file is not referenced within 5 years after the date that it is submitted to FDA, FDA will return the master file to the person who submitted it.

* * * * *

(e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit any update report in electronic format and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA. The time frame for review of a PMA will not be extended due to the submission of an update report unless the update is a major amendment under § 814.37(c)(1). The applicant shall submit these reports—

* * * * *

(f) If a color additive subject to section 721 of the Federal Food, Drug, and Cosmetic Act is used in or on the device and has not previously been listed for such use, then, in lieu of submitting a color additive petition under part 71 of this chapter, at the option of the applicant, the information required to be submitted under part 71 may be submitted as part of the PMA. When submitted as part of the PMA, the information shall be submitted in electronic format. A PMA for a device that contains a color additive that is subject to section 721 of the Federal Food, Drug, and Cosmetic Act will not be approved until the color additive is listed for use in or on the device.

* * * * *

(h) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm.*

* * * * *

■ 9. Amend § 814.39 by revising paragraph (c)(1) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(c)(1) All procedures and actions that apply to an application under § 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under § 814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by FDA. The applicant shall submit a PMA supplement in electronic format and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional information, if requested by FDA, in electronic format. The time frames for review of, and FDA action on, a PMA supplement are the same as those provided in § 814.40 for a PMA.

* * * * *

■ 10. Amend § 814.104 by revising paragraphs (d) introductory text and (d)(1) and (2) to read as follows:

§ 814.104 Original applications.

* * * * *

(d) *Address for submissions and correspondence.* All original HDEs, amendments and supplements, as well as any correspondence relating to an HDE, must be provided in electronic format. These materials must be sent or delivered to one of the following:

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address found on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm.*

* * * * *

Dated: December 9, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27047 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–511]

Technical Correction to Regulation Regarding Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; technical correction.

SUMMARY: This final rule corrects an erroneous cross-reference in a Drug Enforcement Administration regulation involving registration and ocean vessels, aircraft, and other entities. This change will provide clarity.

DATES: This rule is effective December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701

Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances; as well as the maintenance and submission of records and reports of registrants; and that are necessary and appropriate for the efficient execution of his statutory functions. 21 U.S.C. 821, 827, 871(b). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of the DEA. 28 CFR 0.100(b).

Technical Correction

This rule revises a reference to ''§ 1307.11(a)(4)'' in 21 CFR 1301.25(f)(3) to the correct reference, ''§ 1307.11(a)(1)(iv).'' This change is not substantive and is only intended to improve the clarity of 21 CFR 1301.25(f)(3).

Regulatory Analyses

Administrative Procedure Act

The Administrative Procedure Act (APA) (5 U.S.C. 553) does not require notice and the opportunity for public comment where the agency for good cause finds that notice and public comment are unnecessary, impracticable, or contrary to the public interest under 5 U.S.C. 553(b)(B). This rule contains a technical correction; it imposes no new or substantive requirement on the public or DEA registrants. As such, DEA has determined that notice and the opportunity for public comment on this rule are unnecessary. Because this is not a substantive rule and as DEA finds good cause under 5 U.S.C. 553(d)(3) for the above reason, this final rule will take effect upon date of publication in the **Federal Register**.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to, and reaffirms, the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. The Office of Information and Regulatory Affairs has deemed this rulemaking not significant under E.O. 12866. This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Executive Order 12988, Civil Justice Reform

This final rule 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 final rule does not have federalism implications warranting the application of Executive Order 13132. The final rule does not have substantial direct effects on the States, on the relationship between the Federal 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 final rule does not have tribal implications warranting the application of Executive Order 13175. This rule 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 APA, 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

The DEA has determined and certified pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 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 annually for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under the provisions of UMRA.

Paperwork Reduction Act of 1995

This action does not involve a collection of information requirement under the Paperwork Reduction Act, 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 the Congressional Review Act (CRA), 5 U.S.C. 804. 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 United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, the 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 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

§ 1301.25 [Amended]

■ 2. Amend § 1301.25(f)(3) by removing ''1307.11(a)(4)'' and adding in its place ''1307.11(a)(1)(iv)''.

Dated: December 4, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–27097 Filed 12–13–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 52

[Docket No. USCG–2019–0929]

Board for Correction of Military Records; Technical Amendment

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Board for Correction of Military Records of the Coast Guard (BCMR) is updating its mailing address in the Code of Federal Regulations. On April 29, 2019 the BCMR moved from 245 Murray Lane, Washington, DC 20528 to 2707 Martin Luther King Jr. Avenue SE, Washington, DC 20528. This rule only updates the BCMR's mailing address for submitting an application for correction of a Coast Guard record and does not create or change any substantive requirements.

DATES: This final rule is effective on December 16, 2019.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket number USCG–2019–0929, which is available at *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Julia Andrews, Chair, BCMR, telephone 202–447–4099, email at *cgbcmr@hq.dhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Discussion of the Rule

On April 29, 2019 the Board for Correction of Military Records of the Coast Guard (BCMR) mailing address changed from 245 Murray Lane, Washington, DC 20528 to 2707 Martin Luther King Jr. Avenue SE, Stop 0485, Washington, DC 20528–0485. Through this technical amendment, the BCMR is making a corresponding change to the BCMR's mailing address in the Code of Federal Regulations (CFR) in 33 CFR 52.21(a). Section 52.21(a) provides the BCMR mailing address for submitting an application for correction of a Coast Guard record on DD Form 149 (Application for Correction of Military or Naval Record). The BCMR has already updated the mailing address on the DD Form 149 and the BCMR's website to reflect the change in address.

This rule is issued under the authority of 5 U.S.C. 552; 14 U.S.C. 501 and 503; and Department of Homeland Security Delegation Nos. 0160.1 and 0170.1.

II. Regulatory History

The Coast Guard did not publish a notice of proposed rulemaking for this rule. Under Title 5 of the United States Code (U.S.C.), Section 553(b)(A), this final rule is exempt from notice and public comment rulemaking requirements because the change involves rules of agency organization, procedure, or practice. In addition, under 5 U.S.C. 553(b)(B), an agency may waive the notice and comment requirements if it finds, for good cause, that notice and comment is impracticable, unnecessary, or contrary to the public interest. The Coast Guard finds that notice and comment is unnecessary under 5 U.S.C. 553(b)(B) because the mailing address change is an agency procedural correction that will have no substantive effect on the public. For the same reasons, the Coast Guard finds that good cause exists under 5 U.S.C. 553(d) for making this final rule effective immediately upon publication.

III. Regulatory Analyses

The Coast Guard developed this rule after considering numerous statutes and executive orders related to rulemaking. Below are summarized analyses based on these statutes or executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. Because this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. *See* the OMB Memorandum titled ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs''' (April 5, 2017). This rule involves non-substantive changes and internal agency practices and procedures; it will not impose any additional costs on the public. The benefit of the non-substantive change that updates a mailing address is increased clarity and accuracy of regulations for the public.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, the Coast Guard has considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This rule is not preceded by a notice of proposed rulemaking. Therefore, it is exempt from the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act does not apply when notice and comment rulemaking is not required. This rule consists of a technical amendment to a mailing address and does not have any substantive effect on the regulated industry or small businesses.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, the Coast Guard offers to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

D. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.