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You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993-0002, 855-543-3784 or 301-796-3400; Fax: 301-431-6353, email: druginfo@fda.hhs.gov. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Tracy Rupp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5171, Silver Spring, MD 20993, 240-402-0260.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an immediately in effect guidance for industry entitled "Compliance Policy for Certain Compounding of Oral Oxtriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency." This guidance describes FDA's policy concerning the conditions under which the Agency does not generally intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician using the bulk drug substance oxtriptan to compound oral drug products for patients with BH4 deficiency.

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician to qualify for exemptions from certain requirements of the FD&C Act related to FDA approval prior to marketing, current good manufacturing practice requirements, and labeling with adequate directions for use (see sections 505, 501(a)(2)(B), and 502(f)(1) of the

FD&C Act (21 U.S.C. 355, 351(a)(2)(B), and 352(f)(1))). One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that: (1) Comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by FDA; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by FDA, appear on a list of bulk drug substances developed by FDA through regulation. (See section 503A(b)(1)(A)(i) of the FD&C Act.)

On February 19, 2019, FDA issued a final rule (84 FR 4696) ("February 19, 2019, final rule"), which established the list of bulk drug substances that can be used to compound drug products under section 503A of the FD&C Act even though they are not the subject of an applicable USP or NF monograph or a component of an FDA approved drug product (the 503A Bulks List). (See section 503A(b)(1)(A) of the FD&C Act.) The final rule, codified at § 216.23 (21 CFR 216.23), placed six bulk drug substances on the 503A Bulks List (§ 216.23(a)), and identified four others, including oxtriptan, that cannot be used to compound drug products under section 503A of the FD&C Act (§ 216.23(b)). Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of future rulemaking.

FDA developed this guidance in response to communications from pharmacists and caregivers regarding the use of oxtriptan to treat patients with BH4 deficiency following issuance of the February 19, 2019, final rule, which placed oxtriptan on the list of bulk drug substances that cannot be used to compound drug products under section 503A of the FD&C Act. According to those communications and other information available to the Agency, oxtriptan is the standard of care for the treatment of BH4 deficiency, which is caused by several different rare enzyme defects that result from gene mutations. BH4 deficiency is also known as: Primary tetrahydrobiopterin deficiency, atypical phenylketonuria (PKU), GTP cyclohydrolase (GTPCH) deficiency, 6-pyruvoyl-tetrahydropterin synthase (6-PTPS) deficiency, and dihydropteridine reductase (DHPR) deficiency. FDA did not consider BH4

deficiency during its initial review of this substance for the 503A Bulks List. Thus, this guidance addresses the conditions under which FDA does not intend to take regulatory action against a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician for the use of bulk oxtriptan to compound oral drug products for the treatment of identified individual patients with BH4 deficiency provided certain conditions are met. In light of the new information regarding use of oral oxtriptan to treat BH4 deficiency, FDA is considering whether to reevaluate the exclusion of oxtriptan from the 503A Bulks List.

FDA is issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate due to the public health need for patients with BH4 deficiency to access compounded oxtriptan oral drug products (21 CFR 10.115(g)(2)). This guidance does not establish any rights for any person and is not binding on FDA or the public. Although this guidance is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at either <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: July 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG-2016-0989]

RIN 1625-AA01

Anchorage Regulations; Passagassawakeag River, Belfast, ME

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing two special anchorage areas in the Passagassawakeag River in the vicinity of Belfast, ME. This proposed action is necessary to facilitate safe navigation in that area and provide safe and secure anchorages for vessels less than 65 feet in length. This action is intended to increase the safety of life and property in the Passagassawakeag River in the vicinity of Belfast, improve the safety of anchored vessels, and provide for the overall safe and efficient flow of vessel traffic and commerce.

DATES: This rule is effective August 7, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2016-0989 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, contact Mr. Craig Lapiejko, Waterways Management at First Coast Guard District, telephone (617) 223-8351, email craig.d.lapiejko@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 NOAA National Oceanic and Atmospheric Administration
 NPRM Notice of proposed rulemaking
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

In March 2016, the harbor master submitted a draft proposal to the Belfast City Council and subsequently the town began talks with Coast Guard Sector Northern New England regarding establishment of a special anchorage area in Belfast. Subsequently, the Town of Belfast, ME Harbor Committee and the Belfast harbor master petitioned Coast Guard Sector Northern New England to designate a special anchorage area in the Passagassawakeag River, in the vicinity of Belfast, ME. In response, on October 3, 2017, the Coast Guard published a NPRM titled "Special Anchorage Areas; Passagassawakeag River, Belfast Bay, Belfast, Maine" (82 FR 46004). There, we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to establishing two special anchorages in the Passagassawakeag River. During the comment period that ended December 4, 2017, we received one comment. For the

reasons discussed below, the Coast Guard is making no changes to this rule from the proposed rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 471, 2071; 46 U.S.C. 70034 (previously 33 U.S.C. 1231). Commander, First Coast Guard District has determined that this rule will reduce the risk of vessel collisions by creating two special anchorage areas in the Passagassawakeag River in the vicinity of the northeastern portion of Belfast, ME. The purpose of this rule is to increase the safety of life and property in the Passagassawakeag River in the vicinity of Belfast, improve the safety of anchored vessels, and provide for the overall safe and efficient flow of vessel traffic and commerce.

IV. Discussion of Comments, Changes, and the Rule

This rule establishes two special anchorage areas, referred to as special anchorage areas A and B, in the Passagassawakeag River in the vicinity of Belfast, ME. Special anchorage area A is approximately 554,800 sq. yards and is on the north side of the river located between the mouth of the Goose River and Patterson Pt, downstream of the US RT 1 Bridge. Special anchorage area B is approximately 693,889 sq. yards and located along the southern shores of the river located between the Belfast Town docks to Belfast City Park.

Vessels less than 65 feet in length, when at anchor in these special anchorage areas, will not be required to sound signals or display anchorage lights or shapes when at anchor. Additionally, mariners using these anchorage areas are encouraged to contact local and state authorities, such as the local harbor master, to ensure compliance with any additional applicable state and local laws. Such laws may involve, for example, compliance with direction from the local harbor master when placing or using moorings within the anchorage.

The Coast Guard received one comment on our NPRM published on October 3, 2017. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

The one comment was authored by a NOAA cartographer who wanted to make the Coast Guard aware of charted features within the proposed special anchorage areas. Specifically, a charted obstruction (Obstn) feature within special anchorage area A and a charted pier (jetty) in ruins within special anchorage area B.

The Coast Guard and Belfast harbor master are aware of the charted

obstructions. The town of Belfast has operated these areas as managed mooring fields for decades and places the moorings around the charted obstructions. The regulatory text appears at the end of this document. In our note to § 110.4(d), we state that all coordinates referenced use datum NAD 83 and that all anchoring in the areas is under the supervision of the town of Belfast harbor master or other such authority as may be designated by the authorities of the Town of Belfast, Maine. Mariners using these special anchorage areas are encouraged to contact local and state authorities, such as the local harbor master, to ensure compliance with any additional applicable state and local laws.

Additionally during the environmental review process the Coast Guard received comments from the NOAA Habitat Conservation Division. The comments, authored by a NOAA Marine Habitat Resource Specialist, recommended an eelgrass survey be conducted to determine the presence of eelgrass beds. Additionally, the Marine Habitat Resource Specialist recommended the moorings be converted to conservation moorings that use a floating pendant in lieu of chains to prevent damage to eelgrass beds.

An eelgrass study was conducted by the City of Belfast in October, 2018. The study concluded there was no eelgrass within the proposed area. The City of Belfast expressed their intention to continuously monitor the area for potential eelgrass growth.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analysis based on those statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the fact that vessel movement in the area will not be affected. Additionally, those using the waterway will see no adverse changes to how the waterway presently operates.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the Passagassawakeag River in Belfast, ME may be small entities, for the reasons stated above in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). 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.

C. Collection of Information

This rule will not call for a new collection of information under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of two special anchorage areas in the Passagassawakeag River in the vicinity of northeastern Belfast, ME. It is categorically excluded from further review under paragraph L59 (a) in Table 3–1 of U.S. Coast Guard Environmental

Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 2071; 46 U.S.C. 70034; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 110.4 by adding paragraph (d) to read as follows:

§ 110.4 Penobscot Bay, Maine.

* * * * *

(d) *Passagassawakeag River, Belfast Bay, Belfast, Maine*—(1) *Special anchorage area A*. All of the waters enclosed by a line beginning at latitude 44°25′23″ N, longitude 068°58′55″ W; thence to latitude 44°25′30″ N, longitude 068°58′48″ W; thence to latitude 44°25′33″ N, longitude 068°59′15″ W; thence to latitude 44°25′39″ N, longitude 068°59′17″ W; thence to latitude 44°25′48″ N, longitude 068°59′57″ W; thence to latitude 44°25′46″ N, longitude 069°00′08″ W; thence to the point of beginning.

(2) *Special anchorage area B*. All of the waters enclosed by a line beginning at latitude 44°25′17″ N, longitude 068°59′00″ W; thence to latitude 44°24′56″ N, longitude 068°59′23″ W; thence to latitude 44°25′20″ N, longitude 068°59′38″ W; thence to latitude 44°25′44″ N, longitude 069°00′09″ W; thence to the point of beginning.

Note to § 110.4(d): All coordinates referenced use datum: NAD 83. All anchoring in the areas is under the supervision of the town of Belfast harbormaster or other such authority as may be designated by the authorities of the Town of Belfast, Maine. Mariners using these special anchorage areas are encouraged to contact local and state authorities, such as the local harbormaster, to ensure compliance with any additional applicable state and local laws.

Dated: June 28, 2019.

A.J. Tionsgon,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

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