

been declared a designated new animal drug by FDA under section 573(a) of the FD&C Act.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 516 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for "AB Science"; and in the table in paragraph (c)(2), numerically add an entry for "052913" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

Firm name and address	Drug labeler code
* * * * *	
(c) * * *	
(1) * * *	
* * * * *	
AB Science, 3 Avenue George V, 75008 Paris, France	052913
* * * * *	
(2) * * *	
Drug labeler code	Firm name and address
* * * * *	
052913	AB Science, 3 Avenue George V, 75008 Paris, France.
* * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 4. Add § 516.1318 to subpart E to read as follows:

§ 516.1318 Masitinib.

(a) *Specifications.* Each tablet contains 50 or 150 milligrams (mg) masitinib mesylate.

(b) *Sponsor.* See No. 052913 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* 12.5 mg/kilograms (5.7 mg/lb) of body weight daily.

(2) *Indications for use.* For the treatment of recurrent (post-surgery) or nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

Dated: January 28, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–2519 Filed 2–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Restricted Area, Potomac River, Marine Corps Base Quantico, Quantico, VA

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is amending its regulations to establish a restricted area in the waters of the Potomac River extending offshore from the Marine Corps Air Facility (MCAF) at Marine Corps Base Quantico (MCB Quantico), located in Quantico, Virginia. The restricted area will address current security needs at MCB Quantico, including the protection of military assets at MCAF which includes the Presidential Helicopter Squadron (HMX–1). The restricted area will also protect public health by preventing vessels from disturbing a planned

environmental remediation area that is located to the northeast of MCAF.

DATES: *Effective date:* March 7, 2011.

ADDRESSES: Headquarters, U.S. Army Corps of Engineers, Operations and Regulatory Community of Practice, 441 G Street, NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or by e-mail at *david.b.olson@usace.army.mil* or Mr. Steve Elinsky, U.S. Army Corps of Engineers, Baltimore District, Regulatory Branch, at 410–962–4503 or by e-mail at *steve.elinsky@usace.army.mil*.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps is amending its regulations to establish a restricted area in the waters of the Potomac River extending offshore from the MCAF at MCB Quantico, located in Quantico, Virginia. The restricted area will address current security needs at MCB Quantico, including the protection of military assets at MCAF which includes the Presidential Helicopter Squadron (HMX–1). The restricted area will also protect public health by preventing vessels from disturbing a planned environmental remediation area that is located to the northeast of MCAF.

The proposed rule was published in the August 31, 2010, edition of the **Federal Register** (75 FR 53264) and the docket number was COE–2010–0032. In September 2010, the Corps Baltimore and Norfolk districts issued public notices soliciting comments on the proposal from all known interested parties. The districts received three comments.

One commenter indicated that this action does not require essential fish habitat (EFH) conservation measures to protect EFH. Another commenter said that the proposed undertaking would have no effect on historic resources in Maryland. One commenter stated that the establishment of the restricted area would not impact recreation nor would it adversely affect any documented state-listed plant or animal species in Virginia.

None of these comments warrant changes to the rule text. However, to provide clarity in the final rule, the following changes were made to the rule text:

1. The provisions concerning the timing of the restrictions stated in

paragraph (b)(2) of the proposed rule were moved to paragraph (b)(1).

2. The last two sentences of paragraph (a) of the proposed rule were moved to paragraph (b)(2).

3. To clearly indicate that limited access to the restricted area by commercial fishermen may be granted by the Marine Corps, the first sentence of paragraph (b)(3) of the proposed rule was moved to create a new paragraph (d).

4. The following sentence from paragraph (c) of the proposed rule was not included in the final rule to simplify the enforcement provision of this section: "USMC boats with law enforcement personnel will randomly patrol the restricted area and provide a response capability. All persons, vessels, or other craft are prohibited from entering, transiting, drifting, dredging, or anchoring within the restricted area without the permission of the Commander, MCB Quantico or his/her designated representative."

Administrative Requirements

a. *Review Under Executive Order 12866.* This rule is issued with respect to a military function of the Department of Defense, and the provisions of Executive Order 12866 do not apply.

b. *Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 et seq.* This rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96-354), which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.*, small businesses and small governments). The Corps determined that the establishment of the new restricted area zone would not have a significant economic impact on a substantial number of small entities. For more detailed analysis of potential economic impacts of this rule, please see the regulatory analysis in the environmental assessment.

c. *Review Under the National Environmental Policy Act.* An environmental assessment (EA) has been prepared. After considering the comments received in response to the proposed rule, we have concluded that the establishment of a restricted area at MCB Quantico will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement is not required. The final EA and Finding of No Significant Impact may be reviewed at the Baltimore District Office. Please contact Mr. Steve

Elinsky at the phone number specified above for further information.

d. *Unfunded Mandates Reform Act.* This rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Reform Act (Pub. L. 104-4, 109 Stat. 48, 2 U.S.C. 1501 *et seq.*). We have also found, under Section 203 of the Act, that small governments will not be significantly or uniquely affected by this rule.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Transportation, Waterways.

For the reasons stated in the preamble, the Corps amends 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for 33 CFR part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Add § 334.235 to read as follows:

§ 334.235 Potomac River, Marine Corps Base Quantico (MCB Quantico) in vicinity of Marine Corps Air Facility (MCAF), restricted area.

(a) *The area.* All of the navigable waters of the Potomac River extending approximately 500 meters from the high-water mark on the Eastern shoreline of the MCAF, bounded by these coordinates (including the Chopawamsic Creek channel, but excluding Chopawamsic Island): Beginning at latitude 38°29'34.04" N, longitude 077°18'22.4" W (Point A); thence to latitude 38°29'43.01" N, longitude 077°18'4.1" (Point B); thence to latitude 38°29'55.1" N, longitude 077°17'51.3" W (Point C); thence to latitude 38°30'10.1" N, longitude 077°17'40.3" W (Point D); thence to latitude 38°30'23.43" N, longitude 077°17'50.30" W (Point E); then along the western shoreline of Chopawamsic Island to latitude 38°30'35.13" N, longitude 077°17'47.45" W (Point F); thence to latitude 38°30'42.1" N, longitude 077°17'37.1" W (Point G); thence to latitude 38°30'50.71" N, longitude 077°17'54.12" W (Point H); then along the shoreline to latitude 38°30'0.058" N, longitude 077°18'39.26" W (Point I); then across the Chopawamsic Channel to latitude 38°29'58.45" N, longitude 077°18'39.97" W (Point J); thence to latitude 38°29'38.2" N, longitude 077°18'38.14"

W (Point K); and thence to the beginning point of origin.

(b) *The regulations.* (1) All persons, vessels, or other craft are prohibited from entering, transiting, drifting, dredging, or anchoring within the restricted area without the permission of the Commander, MCB Quantico or his/her designated representatives. The restriction will be in place 24 hours a day, seven days a week.

(2) The boundary of the restricted area will be demarcated with marker buoys and warning signs set at 500 foot intervals. In addition, lighted, floating, small craft intrusion barriers will be placed across the Chopawamsic Creek channel at the entrance to the channel from the Potomac River and immediately west of the CSX railroad bridge.

(c) *Enforcement.* The regulations in this section shall be enforced by the Commander, MCB Quantico or any such agencies he/she designates. The areas identified in paragraph (a) of this section will be monitored 24 hours a day, 7 days a week. Any person or vessel encroaching within the areas identified in paragraph (a) of this section will be directed to immediately leave the restricted area. Failure to do so could result in forceful removal and/or criminal charges.

(d) *Exceptions.* Commercial fisherman will be authorized controlled access to the restricted area (with the exception of Chopawamsic Creek channel) after registering with MCB Quantico officials and following specific access notification procedures.

Dated: January 31, 2011.

Michael G. Ensich,

Chief, Operations and Regulatory, Directorate of Civil Works.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 93

[FRL-9261-6]

Official Release of the January 2011 AP-42 Method for Estimating Re-Entrained Road Dust From Paved Roads

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of Availability.

SUMMARY: On January 13, 2011, EPA posted the latest version of the method for estimating re-entrained road dust emissions from cars, trucks, buses, and