

Modesto, CA 95354 has informed FDA of a change of address to 4100 Bangs Ave., Modesto, CA 95356. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 to reflect these changes.

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 Parts 520 and 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 522, and 524 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), remove the entry for “Janssen Pharmaceutica NV” and revise the entry for “Veterinary Service, Inc.”; and in the table in paragraph (c)(2), remove the entry for “012758” and revise the entry for “033008” to read as follows:

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

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * * * *	* * * * *
Veterinary Service, Inc., 4100 Bangs Ave., Mo- desto, CA 95356	033008
* * * * *	* * * * *

(2) * * *

Drug labeler code	Firm name and address
* * * * *	* * * * *

Drug labeler code	Firm name and address
* * * * *	* * * * *
033008	Veterinary Service, Inc., 4100 Bangs Ave., Modesto, CA 95356.
* * * * *	* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.150 [Amended]

■ 4. In paragraph (b) of § 522.150, remove “012578” and in its place add “000986”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 6. In § 524.1445, revise paragraph (b) to read as follows:

§ 524.1445 Miconazole, polymixin B, and prednisolone suspension.

* * * * *
(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.
* * * * *

Dated: August 1, 2012.

Elizabeth Rettie,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2012–19147 Filed 8–3–12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0223]

RIN 1625–AA00

Safety Zone; 2012 Ironman US Championship Swim, Hudson River, Fort Lee, NJ

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the Hudson River in the vicinity of Englewood Cliffs

and Fort Lee, NJ for the 2012 Ironman US Championship swim event. This temporary safety zone is necessary to protect the maritime public and event participants from the hazards associated with swim events. This rule is intended to restrict all vessels and persons from entering into, transiting through, mooring, or anchoring within the safety zone unless authorized by the Captain of the Port (COTP) New York or a designated representative.

DATES: This rule is effective from 6 a.m. until 10 a.m. on August 11, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0223]. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ensign Kimberly Farnsworth, Coast Guard; Telephone (718) 354–4163, email Kimberly.A.Farnsworth@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
CFR Code of Federal Regulations
NPRM Notice of Proposed Rulemaking
COTP Captain of the Port

A. Regulatory History and Information

On June 8, 2012, we published a notice of proposed rulemaking (NPRM) entitled 2012 Ironman US Championship Swim, Hudson River, Fort Lee, NJ in the **Federal Register** (77 FR 34285). We received no comments on the proposed rule. No public meeting was requested and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. This event will occur before 30 days has elapsed after the publication of the rule. The event sponsor is unable and unwilling to postpone this event because the date of this event was

chosen based on optimal tide, current, and weather conditions needed to promote the safety of swim participants. In addition, any change to the date of the event would cause economic hardship on the marine event sponsor and negatively impact other activities being held in conjunction with this event, such as potentially causing numerous event participant cancellations.

B. Basis and Purpose

The legal basis for this rule is 33 U.S.C 1231; 46 U.S.C Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1, which collectively authorizes the Coast Guard to define regulatory safety zones.

The COTP has determined that swim events in close proximity to marine traffic pose significant risk to public safety and property. The combination of increased numbers of recreation vessels, congested waterways, and large numbers of swimmers in the water has the potential to result in serious injuries or fatalities. In order to protect the safety of all waterway users including event participants and spectators, this rule establishes a temporary safety zone for the duration of the event.

C. Discussion of Comments, Changes and the Final Rule

No comments were received. The Coast Guard did not make any changes in this final rule that were not published in the NPRM.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We expect the economic impact of this rule to be very minimal. Although this regulation may have some impact on the public, the potential impact will

be minimized for the following reasons. Vessels will only be restricted from the safety zone for a short duration of time. Before activating the zone, we will notify mariners by appropriate means including but not limited to Local Notice to Mariners and Broadcast Notice to Mariners. Furthermore, vessels may be authorized to transit the zones with permission of the COTP New York or designated representative.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The Coast Guard received no comments from the Small Business Administration on this rule. 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.

(1) This rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Hudson River during the effective period.

(2) This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. This safety zone will be enforced for only 4 hours. Vessel traffic can pass safely through the safety zone with permission from the COTP or a designated representative. Before activating the zone, we will notify mariners by appropriate means including but not limited to Local Notice to Mariners and Broadcast Notice to Mariners.

3. Assistance for Small Entities

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**, above.

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.

4. 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).

5. Federalism

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 determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. 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.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of

Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

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.

12. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (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 establishing a temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREA

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0223 to read as follows:

§ 165.T01–0223 Safety Zone; 2012 Ironman US Championship Swim, Hudson River, Fort Lee, NJ.

(a) *Regulated Area.* All navigable waters of the Hudson River bound by a line drawn from the shoreline of the Palisades Interstate Parkway, approximately 2.8 NM North of the George Washington Bridge, Fort Lee, New Jersey, approximate position 40°53′44.93″ N 073°56′11.79″ W, east to a point 515 yards offshore, approximate position 40°53′40.00″ N 073°55′53.00″ W, south to a position 242 yards offshore, approximate position 40°51′30.00″ N 073°57′09.00″ W, west to the south corner of Ross Dock, Fort Lee, New Jersey, approximate position 40°51′33.77″ N 073°57′16.00″ W, then back to the point of origin.

(b) *Effective Period.* This rule will be effective from 6 a.m. to 10 a.m. on August 11, 2012.

(c) *Definitions.* The following definitions apply to this section:

(1) *Designated Representative.* A “designated representative” is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port Sector New York (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official Patrol Vessels.* Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) *Spectators.* All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(d) *Regulations.* (1) No vessels, except for participating safety vessels, will be allowed to transit the safety zone without the permission of the COTP.

(2) All persons and vessels shall comply with the instructions of the COTP or the designated representative. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing

light, or other means, the operator of a vessel shall proceed as directed.

(3) Vessel operators desiring to enter or operate within the regulated area shall contact the COTP or the designated representative via VHF channel 16 or 718–354–4353 (Coast Guard Sector New York command center) to obtain permission to do so.

Dated: July 19, 2012.

G. Loebel,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2012–19080 Filed 8–3–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Parts 1, 5, 10, 11, and 41

[Docket No. PTO–P–2011–0072]

RIN 0651–AC66

Changes To Implement Miscellaneous Post Patent Provisions of the Leahy-Smith America Invents Act

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Leahy-Smith America Invents Act (AIA) expands the scope of information that any party may cite in a patent file to include written statements of a patent owner filed in a proceeding before a Federal court or the United States Patent and Trademark Office (Office) regarding the scope of any claim of the patent, and provides for how such information may be considered in *ex parte* reexamination, *inter partes* review, and post grant review. The AIA also provides for an estoppel that may attach with respect to the filing of an *ex parte* reexamination request subsequent to a final written decision in an *inter partes* review or post grant review proceeding. The Office is revising the rules of practice to implement these post-patent provisions, as well as other miscellaneous provisions, of the AIA.

DATES: *Effective date:* The changes in this final rule are effective on September 16, 2012.

FOR FURTHER INFORMATION CONTACT: Joseph F. Weiss, Jr. ((571) 272–7759), Legal Advisor, or Pinchus M. Laufer ((571) 272–7726), Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy.

SUPPLEMENTARY INFORMATION: