

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 100–556 and ANADAs 200–435, 200–446, and 200–459, and all supplements and amendments thereto, is withdrawn, effective October 15, 2012. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Modern Veterinary Therapeutics, LLC, and Springfield Milling Corp. will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

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 522 and 524

Animal drugs.

21 CFR Parts 558

Animal drugs, Animal feeds.

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, 522, 524, and 558 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.

§ 510.600 [Amended]

- 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Modern Veterinary Therapeutics, LLC” and “Springfield Milling Corp.”; and in the table in paragraph (c)(2), remove the entries for “015914” and “035955”.

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.

§ 522.246 [Amended]

- 4. In § 522.246, in paragraph (b)(2), remove “Nos. 015914 and 059130” and in its place add “No. 059130”.

§ 522.775 [Amended]

- 5. In § 522.775, in paragraph (b), remove “Nos. 000010 and 015914” and in its place add “No. 000010”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

- 6. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.2483 [Amended]

- 7. In § 524.2483, in paragraph (b), remove “015914.”

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 8. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.625 [Amended]

- 9. In § 558.625, remove and reserve paragraph (b)(40).

Dated: September 27, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–24331 Filed 10–2–12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2012–0728]

RIN 1625–AA08

Special Local Regulations; Red Bull Flugtag Miami, Biscayne Bay; Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the waters of Biscayne Bay, east of Bayfront Park, in Miami, Florida during the Red Bull Flugtag. The Red Bull Flugtag is scheduled to take place on Saturday, November 3, 2012. The event consists of 30 participants launching self-propelled flying machines from a 30ft ramp to the water below. 150 spectator vessels are expected to attend the event. The special local regulation is

necessary to provide for the safety of the participants, participant vessels, and general public on the navigable waters of the United States during the event. The special local regulation will encompass the following two areas: An event area, where non-participant vessels are prohibited from entering, transiting through, anchoring in, or remaining within; and a spectator area, where all vessels are permitted to anchor.

DATES: This rule is effective and will be enforced from 11 a.m. to 4 p.m. on November 3, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0728]. 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 Lieutenant Mike H. Wu, Sector Miami Prevention Department, Coast Guard; telephone 305–535–7576, email Mike.H.Wu@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
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive all event details until September 5, 2012. As a

result, the Coast Guard did not have sufficient time to publish an NPRM and to receive public comments prior to the event. Any delay in the effective date of this rule would be contrary to the public interest because immediate action is needed to minimize potential danger to the participants, participant vessels, spectators, and the general public.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish special local regulations: 33 U.S.C. 1233. The purpose of the rule is to provide for the safety of life on navigable waters of the United States during the Red Bull Flugtag.

C. Discussion of the Final Rule

On November 3, 2012, Red Bull North America is sponsoring the Red Bull Flugtag. The event will be held on the waters of Biscayne Bay, Miami, Florida. The event consists of 30 participants launching self-propelled flying machines from a 30ft ramp to the water below. 150 spectator vessels are expected to attend the event.

The special local regulation will encompass certain waters of Biscayne Bay, Miami, Florida. The special local regulation will be enforced from 11 a.m. until 4 p.m. on November 3, 2012. The special local regulation will encompass the following two areas: (1) An event area, where non-participant vessels are prohibited from entering, transiting through, anchoring in, or remaining within; and (2) a spectator area, where vessels are permitted to anchor. Non-participant persons and vessels may request authorization to enter, transit through, anchor in, or remain within the event area by contacting the Captain of the Port Miami via telephone at 305-535-4472, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the event area is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the special local regulations by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses

based on these statutes and 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.

The economic impact of this rule is not significant for the following reasons: (1) The special local regulation will be enforced for only five hours; (2) although non-participant persons and vessels will not be able to enter, transit through, anchor in, or remain within the event area without authorization from the Captain of the Port Miami or a designated representative, they may operate in the surrounding area during the enforcement period; (3) non-participant persons and vessels may still enter, transit through, anchor in, or remain within the event area during the enforcement period if authorized by the Captain of the Port Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the special local regulations to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

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 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 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. 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 Biscayne Bay from 11 a.m. to 4 p.m. on November 3, 2012.

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.ID, 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 a special local regulation issued in

conjunction with a regatta or marine parade. This rule is categorically excluded from further review under paragraph 35(b) and 34(h) 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 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a temporary § 100.35T07-0728 to read as follows:

§ 100.35T07-0728 Special Local Regulation; Red Bull Flugtag, Biscayne Bay; Miami, FL.

(a) *Regulated Area.* The following regulated areas are established as special local regulation. All coordinates are North American Datum 1983.

(1) *Event Area.* All waters of Biscayne Bay, Miami, FL between Bayfront Park and the Intercontinental-Miami Hotel encompassed within an imaginary line connecting the following points: Starting at point 1 in position 25°46'32" N, 80°11'06" W; thence southeast to point 2 in position 25°46'30" N, 80°11'04" W; thence south to point 3 in position 25°46'26" N, 80°11'04" W; thence southwest to point 4 in position 25°46'25" N, 80°11'06" W; thence north back to origin. All non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the event area without authorization from the Captain of the Port Miami or a designated representative.

(2) *Spectator Area.* All waters of Biscayne Bay, Miami, FL between Bayfront Park and the Intercontinental-Miami Hotel encompassed within an imaginary line connecting the following points: Starting at point 1 in position 25°46'32" N, 80°11'05" W; thence northeast to point 2 in position 25°46'36" N, 80°11'01" W; thence south to point 3 in position 25°46'22" N, 80°11'01" W; thence southwest to point

4 in position 25°46'18" N, 80°11'04" W; thence west to point 5 in position 25°46'18" N, 80°11'05" W; thence north to point 6 in position 25°46'25" N, 80°11'06" W; thence northeast to point 7 in position 25°46'26" N, 80°11'04" W; thence northwest to point 8 in position 25°46'30" N, 80°11'04" W; thence northwest back to origin. Vessels are permitted to anchor in this area.

(b) *Definition.* The term "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated areas.

(c) *Regulations.* (1) Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the event area by contacting the Captain of the Port Miami by telephone at 305-535-4472, or a designated representative via VHF radio on channel 16. If authorization is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(2) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement Date.* This rule will be enforced from 11:00 a.m. until 4:00 p.m. on November 3, 2012.

Dated: September 19, 2012.

C.P. Scraba,

Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2012-24343 Filed 10-2-12; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 9

RIN 2900-AN40

Servicemembers' Group Life Insurance and Veterans' Group Life Insurance—Slayer's Rule Exclusion

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations governing Servicemembers' Group Life Insurance (SGLI) and Veterans' Group Life Insurance (VGLI) to prohibit payment of insurance proceeds payable