

Indianapolis, IN 46285. Accordingly, the Agency is amending the regulations in 21 CFR parts 522 and 524 to reflect the transfers of ownership.

Following these changes of sponsorship, Alstoe, Ltd., Animal Health, and Nexcyon Pharmaceuticals, Inc., are no longer sponsors of approved NADAs. Accordingly, FDA is amending 21 CFR 510.600 to remove the entries for these firms.

In addition, Sogeval S.A. is now a sponsor of approved NADAs. Accordingly, FDA is amending 21 CFR 510.600 to add entries for this firm.

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.

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 the table in paragraph (c)(1) of § 510.600, remove the entries for “Alstoe, Ltd., Animal Health” and “Nexcyon Pharmaceuticals, Inc.”, and alphabetically add an entry for “Sogeval S.A.”; and in the table in paragraph (c)(2), remove the entries for “050929” and “062408”, and numerically add an entry for “059120” 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
* * * * *	*
Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France	059120
* * * * *	*

(2) * * *

Drug labeler code	Firm name and address
* * * * *	*
059120	Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France.
* * * * *	*

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.

§ 522.1182 [Amended]

■ 4. In § 522.1182, in paragraphs (b)(3) and (b)(8), remove “062408” and in its place add “059120”.

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.

§ 524.916 [Amended]

■ 6. In paragraph (b) of § 524.916, remove “050929” and in its place add “000986”.

Dated: July 17, 2013.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
 [FR Doc. 2013–17754 Filed 7–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0636]

RIN 1625–AA00

Safety Zone; Metedeconk River; Brick Township, NJ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the enforcement date of a safety zone for one recurring fireworks display in the Fifth Coast Guard District. This regulation applies to only one recurring fireworks event held in the Metedeconk River in Brick Township, NJ. The fireworks display is normally held on the first Thursday in September, but this year it will be held on July 25th. The safety zone is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of Delaware River near Philadelphia, Pennsylvania, during the event.

DATES: This rule is effective from 6:30 p.m. on July 25, 2013 through September 5, 2013. Within the Coast Guard Sector Delaware Bay-COTP Zone portion of the table in 33 CFR 165.506, an entry 19 for the Metedeconk River, Brick Township, NJ Safety Zone will be added from 6:30 p.m. until 10 p.m. on July 25, 2013, and existing entry 9 will be suspended on September 5, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2013–0636]. 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 Veronica Smith, U.S. Coast Guard Sector Delaware Bay, Chief of Waterways Management Division; telephone (215) 271–4851, email veronica.l.smith@uscg.mil. If you have questions on viewing or submitting material to the docket, call Barbara

Hairston, 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 temporary 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 it is impracticable. Publishing an NPRM is impracticable given that the necessary information for this event were not received by the Coast Guard with insufficient time remaining to issue an NPRM. Immediate action is necessary to provide for the safety of life and property in the navigable water. Delaying this rule to wait for a notice and comment period to run would inhibit the Coast Guard’s ability to protect the public from the hazards associated with this maritime fireworks display.

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**. Delaying the establishment of the safety zone is impracticable and contrary to the public interest. Delay could result in mariners approaching the fireworks location, creating a hazardous scenario with potential for loss of life and property. For the same reasons discussed in the preceding paragraph, a 30 day notice period would be impracticable and contrary to the public interest.

B. Basis and Purpose

Recurring fireworks displays are frequently held on or adjacent to the navigable waters within the boundary of the Fifth Coast Guard District. For a description of the geographical area of each Coast Guard Sector—Captain of the Port (COTP) Zone, please see 33 CFR 3.25.

The regulation listing annual fireworks displays within the Fifth Coast Guard District and safety zones locations is 33 CFR 165.506. The Table

to § 165.506 identifies fireworks displays by COTP zone, with the COTP Delaware Bay zone listed in section “(a)” of the Table.

Township of Brick sponsors an annual fireworks display held on the first Thursday in September over the waters of the Metedeconk River, Brick Township, New Jersey. The Table to § 165.506, at section (a) event number “9”, describes the enforcement date and regulated location for this fireworks event.

In the Table, this fireworks display occurs annually on the first Thursday in September. However, this year, the fireworks event will be held on July 25, 2013.

A fleet of spectator vessels are anticipated to gather nearby to view the fireworks display. Due to the need for vessel control during the fireworks display, vessel traffic will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels. Under provisions of 33 CFR 165.506, during the enforcement period, vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander.

C. Discussion of the Final Rule

The Coast Guard will temporarily suspend the regulation listed in Table to § 165.506, section (a) event Number “9”, and insert this temporary regulation at Table to § 165.506, at section (a.) as event Number “19”, in order to reflect that the safety zone will be effective and enforced from 6:30 p.m. until 10 p.m. on July 25, 2013. This change is needed to accommodate the sponsor’s event plan. No other portion of the Table to § 165.506 or other provisions in § 165.506 shall be affected by this regulation.

The regulated area of this safety zone includes all the waters of the Metedeconk River within a 300 yard radius of the fireworks launch platform in approximate position latitude 40°03’24” N, longitude 074°06’42” W, near the shoreline at Brick Township, NJ.

This safety zone will restrict general navigation in the regulated area during the fireworks event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the effective period. The regulated area is needed to control vessel traffic during the event for the safety of participants and transiting vessels.

In addition to notice in the **Federal Register**, the maritime community will be provided extensive advance

notification via the Local Notice to Mariners, and marine information broadcasts so mariners can adjust their plans accordingly.

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 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.

This rule prevents traffic from transiting a portion of the Metedeconk River, in Brick Township, New Jersey during the specified event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via marine information broadcasts, local radio stations and area newspapers so that mariners can adjust their plans accordingly. Additionally, this rulemaking changes the enforcement date for the Metedeconk River, Brick Township, New Jersey fireworks demonstration for July 25, 2013 only and does not change the permanent enforcement period that has been published in 33 CFR 165.506, Table to § 165.506 at section (a), event Number “9”. In some cases vessel traffic may be able to transit the regulated area when the Coast Guard Patrol Commander deems it is safe to do so.

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 small vessels intending to transit or anchor in the Metedeconk River, in Brick Township, New Jersey, where fireworks events are being held. This regulation will not have a significant impact on a substantial number of small entities because it will be enforced only during the fireworks display event that has been permitted by the Coast Guard Captain of the Port. The Captain of the Port will ensure that small entities are able to operate in the regulated area when it is safe to do so. In some cases, vessels will be able to safely transit around the regulated area at various times, and, with the permission of the Patrol Commander, vessels may transit through the regulated area. Before the enforcement period, the Coast Guard will issue maritime advisories so mariners can adjust their plans accordingly.

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 the establishment of a 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**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, 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 AREAS

- 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. In § 165.506, amend the Table to § 165.506 under the heading (a) Coast Guard Sector Delaware Bay—COTP Zone by—
 - a. Suspending entry 9, “Metedeconk River, Brick Township, NJ Safety Zone” on September 5, 2013.
 - b. Adding entry 19 from 6:30 p.m. until 10 p.m. on July 25, 2013, to read as follows:

§ 165.506 Safety Zones; Fireworks Displays in the Fifth Coast Guard District.

* * * * *

Number	Date	Location	Regulated area
(a) Coast Guard Sector Delaware Bay—COTP Zone			
19	July 25th	Metedeconk River, Brick Township, NJ, Safety Zone.	The waters of the Metedeconk River within a 300 yard radius of the fireworks launch platform in approximate position latitude 40°03'24" N, longitude 074°06'42" W, near the shoreline at Brick Township, NJ.

* * * * *

Dated: July 11, 2013.
K. Moore,
Captain, U.S. Coast Guard, Captain of the Port, Delaware Bay.
 [FR Doc. 2013-17677 Filed 7-23-13; 8:45 am]
BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2013-0611]

RIN 1625-AA00

Safety Zone; Joint Operations Exercise, Lake Michigan, IL

AGENCY: Coast Guard, DHS.
ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Michigan near Lake Forest, IL. This safety zone is intended to restrict vessels from a portion of Lake Michigan due to a joint operations exercise involving the Department of Defense and the Department of Homeland Security. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the exercise.

DATES: This rule is effective from 12 p.m. until 11:59 p.m. on July 25, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG-2013-0611. 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 temporary rule, contact or email MST1 Joseph McCollum, U.S. Coast Guard Sector Lake Michigan, at 414-747-7148 or Joseph.P.McCollum@uscg.mil. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
 DOD Department of Defense
 FR Federal Register
 NPRM Notice of Proposed Rulemaking
 TFR Temporary Final Rule

A. Regulatory History and Information

The Coast Guard is issuing this temporary 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 an NPRM with respect to this rule because doing so would be impracticable. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard's ability to protect persons and vessels from the hazards associated with a joint DHS/DOD exercise, which are discussed further below.

Under 5 U.S.C. 553(d)(3), The Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the

Federal Register. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish regulated navigation areas and limited access areas: 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.

On July 25, 2013, personnel and vessels from the Coast Guard and the Department of Defense will participate in a joint exercise involving parachuting personnel over the waters of Lake Michigan, approximately 9.5 nautical miles east of Lake Forest, IL. Coast Guard and DOD vessels are expected to maneuver over a 2 nautical mile section of Lake Michigan in an effort to recover and otherwise aid the personnel in parachutes. The Captain of the Port, Lake Michigan, has determined that parachuting personnel, and the military vessels maneuvering to aid in their recovery, presents a significant risk to public safety and property. Such hazards include collisions among transiting civilian and military vessels, and collisions among parachuting personnel and transiting watercraft.

C. Discussion of the Final Rule

With the aforementioned hazards in mind, the Captain of the Port, Lake Michigan, has determined that this temporary safety zone is necessary to ensure the safety of persons and vessels during the exercise. This zone will be effective and enforced from 12 p.m. until 11:59 p.m. on July 25, 2013. This zone will encompass all waters of Lake Michigan within a 2 Nautical Mile radius of an approximate position at 42°15'01" N, 87°36'0" W (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the