

B will grant A an exclusive license to all of B's patent rights for all veterinary indications. B retains all patent rights for all human indications. The exclusive license to all commercially significant rights for all veterinary indications is an asset acquisition because A is receiving all rights to the patent for a therapeutic area.

3. B holds a patent relating to a biological product. B will grant A an exclusive license to all of B's patent rights in all therapeutic areas. A and B are also entering into a co-development and co-commercialization agreement under which B will assist A in developing, marketing and promoting the product to physicians. B cannot separately use the patent in the same therapeutic area as A under the co-development and co-commercialization agreement. A will book all sales of the product and will pay B a portion of the profits resulting from those sales. Despite B's retention of these co-rights, A is still receiving all commercially significant rights. The licensing agreement is an asset acquisition. This would be an asset acquisition even if B also retained limited manufacturing rights.

4. B holds a patent relating to an active pharmaceutical ingredient and a bulk compound that contains that active pharmaceutical ingredient. B will grant A an exclusive license to use the bulk compound to manufacture and sell a finished product in the neurological therapeutic area. B cannot manufacture the active pharmaceutical ingredient or bulk compound for any other finished products in the neurological area, but it can manufacture either for use by another party in a different therapeutic area. Despite B's retention of manufacturing rights of the active pharmaceutical ingredient and bulk compound for therapeutic areas other than neurology, A is still receiving all commercially significant rights in a therapeutic area and the licensing agreement is the acquisition of an asset.

5. B holds a patent related to a pharmaceutical product that has been approved by the FDA. B will enter into an exclusive distribution agreement with A that will give A the right to distribute the product in the U.S. B will manufacture the product for A and will receive a portion of all revenues from the sale of the product. A receives no exclusive patent rights under the distribution agreement. A has not obtained all commercially significant rights to the patent because it is only handling the logistics of selling and distributing the product on B's behalf.

Therefore, the distribution agreement is not an asset acquisition.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2012-20192 Filed 8-17-12; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2012-0653]

RIN 1625-AA00

Safety Zone; Embry-Riddle Wings and Waves, Atlantic Ocean; Daytona Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the waters of the Atlantic Ocean east of Daytona Beach, Florida during the Embry-Riddle Wings and Waves air show. The event is scheduled to take place from Thursday, October 11, 2012, through Sunday, October 14, 2012. This temporary safety zone is necessary for the safety of air show participants, participant vessels, spectators, and the general public during the event. Persons and vessels that are not participating in the air show will be prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Jacksonville or their designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before August 27, 2012. Requests for public meetings must be received by the Coast Guard on or before August 24, 2012.

ADDRESSES: You may submit comments identified by docket number (USCG-2012-0653) using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail or Delivery:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal

holidays. The telephone number is 202-366-9329.

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Lieutenant Commander Robert Butts, Sector Jacksonville Office of Waterways Management, Coast Guard; telephone 904-564-7563, email Robert.S.Butts@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. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, type the docket number USCG-2012-0653 in the

“SEARCH” box and click “SEARCH.” Click on “Submit a Comment” on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number USCG–2012–0653 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.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before August 22, 2012, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard’s authority to establish regulated navigation areas and other 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; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

The purpose of the rule is to protect the public from the hazards associated with airborne acrobatic maneuvers over the navigable waters of the United States.

C. Discussion of Proposed Rule

On October 11, 2012, through October 14, 2012, the city of Daytona Beach will host an air show event over the Atlantic Ocean in Daytona Beach, FL. In recent years, there have been unfortunate instances of jets and planes crashing during performances at air shows. Along with a jet or plane crash, there is typically a wide area of scattered debris that can damage property and could cause significant injury or death to mariners observing the air shows.

The proposed rule would establish a safety zone that will encompass certain waters of the Atlantic Ocean near Daytona Beach, Florida. The safety zone is necessary to protect the general public from hazards associated with the air show. The safety zone would be enforced from 9:30 a.m. to 5:30 p.m. daily on October 11, 2012, through October 14, 2012. All persons and vessels, are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone, unless authorized by the Captain of the Port Jacksonville or a designated representative. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the safety zone by contacting the Captain of the Port Jacksonville by telephone at 904–564–7511, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the event area is granted by the Captain of the Port Jacksonville or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Jacksonville or a designated representative. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

The final rule may not be published 30 days before the event and the effective date of this proposed rule as is generally required by 5 U.S.C. 553(d)(3). The Coast Guard will accept comments on this shortened period and address them in the final rule.

D. Regulatory Analyses

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

based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed 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 proposed rule is not significant for the following reasons: (1) The safety zone will be enforced for only eight hours on each of the four days of the event; (2) although 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 Jacksonville or a designated representative, they may operate in the surrounding area during the enforcement period; (3) 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 Jacksonville 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

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

The Coast Guard certifies under section 5 U.S.C. 605(b) that this rule will not have a significant economic impact upon a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of the Atlantic Ocean encompassed within the safety zone from 9:30 a.m. to 5:30 p.m. daily on October 11, 2012 through October 14, 2012. For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would 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 proposed 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 From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed rule is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did

not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed 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 made a preliminary determination 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 proposed rule involves establishing a temporary safety zone that will be enforced during the specified operating hours of the event. 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

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add a temporary § 165.T07–0653 to read as follows:

§ 165.T07–0653 Safety Zone; Embry Riddle Wings and Waves, Atlantic Ocean, Daytona Beach, FL.

(a) *Regulated Area.* The following regulated area is a safety zone. All waters of the Atlantic Ocean located east of Daytona Beach, Florida encompassed within an imaginary line connecting the following points: starting at Point 1 in position 29°14′25.79″ N, 081°00′42.75″ W, then east to 29°14′37.53″ N, 081°00′11.64″ W, then south to 29°13′24.78″ N, 080°59′35.95″ W, then west to 29°13′13.04″ N,

081°00'07.05" W, then North back to the original point.

(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 Jacksonville in the enforcement of the regulated area.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Jacksonville or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Jacksonville by telephone at 904-564-7511, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Jacksonville or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Jacksonville or a designated representative.

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

(d) *Effective Date and Enforcement Periods.* This rule is effective from 9:30 a.m. on October 11, 2012, through 5:30 p.m. on October 14, 2012. This rule will be enforced daily from 9:30 a.m. to 5:30 p.m. on October 11, 2012, through October 14, 2012.

Dated: July 26, 2012.

R.E. Holmes,

Commander, U.S. Coast Guard, Acting Captain of the Port Jacksonville.

[FR Doc. 2012-20348 Filed 8-17-12; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2012-0660]

RIN 1625-AA00

Safety Zone; Jacksonville Sea and Sky Spectacular, Atlantic Ocean; Jacksonville Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the waters of the Atlantic Ocean east of Jacksonville Beach, Florida during the Jacksonville Sea and Sky Spectacular air show. The event is scheduled to take place from Friday, October 19, 2012, through Sunday, October 21, 2012. This temporary safety zone is necessary for the safety of air show participants, participant vessels, spectators, and the general public during the event. Persons and vessels will be prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Jacksonville or their designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before September 7, 2012. Requests for public meetings must be received by the Coast Guard on or before August 24, 2012.

ADDRESSES: You may submit comments identified by docket number USCG-2012-0660 using any one of the following methods:

(1) *Federal eRulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail or Delivery:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202-366-9329.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Lieutenant Commander Robert Butts, Sector Jacksonville Office of Waterways Management, Coast Guard; telephone 904-564-7563, email

Robert.S.Butts@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.

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2. Viewing Comments and Documents

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