

paste for the treatment of protozoal myeloencephalitis in horses.

**DATES:** This rule is effective August 21, 2001.

**FOR FURTHER INFORMATION CONTACT:**

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

**SUPPLEMENTARY INFORMATION:** Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141-188 that provides for veterinary prescription use of Marquis™ (ponazuril) EPM Paste for the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*. The NADA is approved as of July 19, 2001, and the regulations are amended in 21 CFR part 520 by adding § 520.1855 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 19, 2001, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 in 21 CFR Part 520**

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 part 520 is amended as follows:

**PART 520—ORAL DOSAGE FORM  
NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.1855 is added to read as follows:

**§ 520.1855 Ponazuril.**

(a) *Specifications.* Each gram of paste contains 150 milligrams (mg) ponazuril.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* 5 mg per kilogram body weight, daily for 28 days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 1, 2001.

**Linda Tollefson,**

*Deputy Director, Center for Veterinary Medicine.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 165**

[COTP Western Alaska-01-002]

**RIN 2115-AA97**

**Safety Zone; Gulf of Alaska, Southeast of Narrow Cape, Kodiak Island, AK**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska. The zone is needed to protect the safety of persons and vessels operating in the vicinity of the safety zone during a rocket launch from the Alaska Aerospace Development Corporation, Narrow Cape, Kodiak Island facility. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Commander, Seventeenth Coast Guard District, or the Coast Guard Captain of the Port, Western Alaska, or his on scene representative. The intended affect of the safety zone is to ensure the safety of

human life and property during the rocket launch.

**DATES:** This temporary final rule is effective from 2 p.m. on August 31, 2001, until 7:30 p.m. on September 15, 2001.

**ADDRESSES:** Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket COTP Western Alaska-01-002 and are available for inspection or copying at Coast Guard Marine Safety Office Anchorage, 510 "L" Street, Suite 100, Anchorage, AK 99501 between 7:30 a.m. to 4 p.m. Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LCDR Diane Kalina, Marine Safety Office Anchorage, at (907) 271-6700.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation. Good cause exists for not publishing a NPRM and for making this regulation effective in less than 30 days after **Federal Register** publication. The parameters of the zone will not unduly impair business and transits of vessels. The Coast Guard will announce via Broadcast Notice to Mariners the anticipated date and time of each launch and will grant general permission to enter the safety zone during those times in which the launch does not pose a hazard to mariners. Because the hazardous condition is expected to last for approximately 5 hours of each day for 16 days, and because general permission to enter the safety zone will be given during non-hazardous times, the impact of this rule on commercial and recreational traffic is expected to be minimal. Therefore, notice and comment is unnecessary. Additionally, the process of scheduling a rocket launch is uncertain due to unforeseen delays that can cause cancellation of the launch. Any delay encountered in this regulation's effective date would be unnecessary and contrary to public interest since immediate action is needed to protect human life and property from possible fallout from the rocket launch. This safety zone should have minimal impact on vessel transits and announcements via Broadcast Notice to Mariners will give vessels advanced notice of the launch.

**Background and Purpose**

The Alaska Aerospace Development Corporation (AADC) will attempt to launch an unmanned rocket from their

facility at Narrow Cape, Kodiak Island, Alaska sometime between 5 p.m. and 7 p.m. each day between August 31, 2001 and September 15, 2001. The safety zone is necessary to protect spectators and transiting vessels from the potential hazards associated with the launch.

The Coast Guard will announce via Broadcast Notice to Mariners the anticipated date and time of the launch and will grant general permission to enter the safety zone during those times in which the launch does not pose a hazard to mariners. Because the hazardous condition is expected to last for approximately 5 hours of each day for 16 days, and because general permission to enter the safety zone will be given during non-hazardous times, the impact of this rule on commercial and recreational traffic is expected to be minimal.

### Discussion of Regulation

From the latest information received from the Alaska Aerospace Development Corporation, the launch window is scheduled for 5 hours each day between August 31, 2001 and September 15, 2001. The size of the safety zone has been set based upon the trajectory information in order to provide a greater safety buffer in the event that the launch is aborted shortly after take-off. The safety zone includes an area in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska. Specifically, the zone encompasses all waters of the Gulf of Alaska that are within the area bounded by a line drawn from a point located at 57° 28' North, 152° 25' West, thence south to a point located at 57° 09' North, 152° 25' West, thence northeast to a point located at 57° 14.5' North, 151° 59' West, thence north northeast to a point located at 57° 28' North, 151° 51.5' West, and thence west to the point located at 57° 28' North, 152° 25' West. All coordinates reference Datum: NAD 1983.

This safety zone is necessary to protect spectators and transiting vessels from the potential hazards associated with the launch of the rocket. The Coast Guard will announce via Broadcast Notice to Mariners the anticipated date and time of the launch and will grant general permission to enter the safety zone during those times in which the launch does not pose a hazard to mariners.

### Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that

order. The Office of Management and Budget has not reviewed it under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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 will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit, anchor, or fish in a portion of the Gulf of Alaska off Ugak Island and Narrow Cape from 2 p.m. to 7:30 p.m. from August 31, 2001 to September 15, 2001. Because the hazardous condition is expected to last for approximately five hours of each day for sixteen days, and because general permission to enter the safety zone will be given during non-hazardous times, the impact of this rule on commercial and recreational traffic should be minimal. Before the effective period, we will issue maritime advisories widely available to users of the affected portion of the Gulf of Alaska. We believe there will be minimal impact to small entities.

### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

### Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

### 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 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.

### Taking of Private Property

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

### 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.

### 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 economically significant and does not cause an environmental risk to health or risk to safety that may disproportionately affect children.

### Consultation and Coordination With Indian Tribal Governments

This 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.

### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions

Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under Figure 2-1, paragraph 34(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. This rule is excluded under paragraph (34)(g) because it is a safety zone. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under ADDRESSES.

#### List of Subjects in 33 CFR Part 165

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

For the reasons set out 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; 50 U.S.C. 191, 33 CFR 1.05-1(g), 6.401-1, 6.04-6, 160.5; 49 CFR 1.46.

2. Add temporary § 165.T-01-002 to read as follows:

#### § 165.T-01-002 Safety Zone: Alaska Aerospace Development Corporation, Narrow Cape, Kodiak Island, AK.

(a) *Description.* This safety zone includes an area in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska. Specifically, the zone includes the waters of the Gulf of Alaska that are within the area bounded by a line drawn from a point located at 57° 28' North, 152° 25' West, thence south to a point located at 57° 09' North, 152° 25' West, thence northeast to a point located at 57° 14.5' North, 151° 59' West, thence north northeast to a point located at 57° 28' North, 151° 51.5' West, and thence west to the point located at 57° 28' North, 152° 25' West.

All coordinates reference Datum: NAD 1983.

(b) *Effective dates.* This section is effective from 2 p.m. on August 31, 2001, until 7:30 p.m. on September 15, 2001.

#### (c) Regulations.

(1) The Captain of the Port and the Duty Officer at Marine Safety Office, Anchorage, Alaska can be contacted at telephone number (907) 271-6700.

(2) The Captain of the Port may authorize and designate any Coast Guard commissioned, warrant, or petty officer to act on his behalf in enforcing the safety zone.

(3) The general regulations governing safety zones contained in Title 33 Code of Federal Regulations, § 165.23 apply. No person or vessel may enter or remain in this safety zone, with the exception of attending vessels, without first obtaining permission from the Captain of the Port or his on scene representative. In the vicinity of Narrow Cape, the Captain of the Port, Western Alaska's on scene representative may be contacted onboard the U. S. Coast Guard cutter via VHF marine channel 16.

Dated: August 6, 2001.

**W.J. Hutmacher,**

*Captain, U.S. Coast Guard, Captain of the Port, Western Alaska.*

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**BILLING CODE 4910-15-U**

#### DEPARTMENT OF TRANSPORTATION

#### Coast Guard

#### 33 CFR Part 165

[CGD09-01-055]

RIN 2115-AA97

#### Safety Zone; Sister Bay MarinaFest, Sister Bay, Wisconsin

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone in Sister Bay for the Sister Bay MarinaFest 2001 fireworks display. This safety zone is necessary to protect spectators and vessels from the hazards associated with the storage, preparation, and launching of fireworks. This safety zone is intended to restrict vessel traffic from a portion of the Sister Bay marina, Sister Bay, Wisconsin.

**DATES:** This temporary rule is effective from 8:30 p.m. until 10 p.m. (CST) on September 1, 2001.

**ADDRESSES:** Comments and material received from the public, as well as documents indicated in this preamble as

being available in the docket, are part of docket [CGD09-01-055] and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207 between 7 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

LCDR Timothy Sickler, Port Operations Chief, Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207. The phone number is (414) 747-7155.

#### SUPPLEMENTARY INFORMATION:

#### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The permit application did not allow sufficient time for publication of an NPRM followed by a temporary final rule effective 30 days after publication. Any delay of the effective date of this rule would be contrary to the public interest by exposing the public to the known dangers associated with fireworks displays and the possible loss of life, injury, and damage to property.

#### Background and Purpose

This safety zone is established to safeguard the public from the hazards associated with launching of fireworks by Sister Bay marina, Sister Bay, Wisconsin. The size of the zone was determined by using previous experiences with fireworks displays in the Captain of the Port Milwaukee zone and local knowledge about wind, waves, and currents in this particular area.

The safety zone will be in effect on September 1, 2001, from 8:30 p.m. until 10 p.m. (CST). The safety zone will encompass all waters bounded by the arc of a circle with a 420-foot radius with its center in approximate position 45° 10.60' N, 087° 06.60' W, offshore Sister Bay marina, Sister Bay, Wisconsin. The size of this zone was determined using the National Fire Prevention Association guidelines and local knowledge concerning wind, waves, and currents. These coordinates are based upon North American Datum 1983 (NAD 83).

All persons and vessels shall comply with the instructions of the Captain of the Port Milwaukee or his designated on scene patrol personnel. Entry into, transiting, or anchoring within the safety zone is prohibited unless