

Eileen M. Albanese,
Director for Office of Exporter Services.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Spectinomycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to correct an error in the indications for use for spectinomycin oral solution in swine. FDA is also amending the regulations for other oral dosage forms of spectinomycin to reflect a current format. These actions are being taken to improve the accuracy and readability of the animal drug regulations.

DATES: This rule is effective February 5, 2008.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has noticed that the animal drug regulations do not reflect the approved indications for use for spectinomycin oral solution in swine. At this time, FDA is amending the animal drug regulations in § 520.2123c (21 CFR 520.2123c) to correct this error. FDA is also amending the regulations in § 520.2123a for spectinomycin tablets and in § 520.2123b for spectinomycin powder to reflect a current format. These actions are being taken to improve the accuracy and readability of the animal drug regulations.

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 the 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. Revise § 520.2123 to read as follows:

§ 520.2123 Spectinomycin oral dosage forms.

■ 3. Revise § 520.2123a to read as follows:

§ 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride pentahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.

(2) *Indications for use.* For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 4. Revise § 520.2123b to read as follows:

§ 520.2123b Spectinomycin powder.

(a) *Specifications.* Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in chickens.* It is administered in the drinking water of growing chickens as follows:

(1) *Indications for use and amounts—(i)* For increased rate of weight gain and improved feed efficiency in broiler chickens, administer 0.5 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(ii) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.

(iii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life

and for 1 day following each vaccination.

(2) *Limitations.* Do not administer to laying chickens. Do not administer within 5 days of slaughter.

■ 5. Revise § 520.2123c to read as follows:

§ 520.2123c Spectinomycin solution.

(a) *Specifications.* Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 000856, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in swine—(1) Amount.* Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.

(2) *Indications for use.* For the treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin in pigs under 4 weeks of age.

(3) *Limitations.* Do not administer to pigs over 15 lb body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

Dated: January 24, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket No. USCG-2007-0036, formerly CGD07-122]

RIN 1625-AA01

Anchorage Regulation; Port Everglades, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard amends the anchorage regulations for Port Everglades, Florida. The amendment modifies the current anchorage area by eliminating that portion of the anchorage closest to sensitive coral reef areas, expands that portion of the anchorage area that poses less risk to these areas, and limits the amount of time a vessel may remain in the anchorage area. These changes ensure

all vessels have fair access to the anchorage area, and provide a higher degree of vessel and environmental safety by reducing the possibility of vessels grounding in sensitive coral reef areas.

DATES: This rule is effective March 6, 2008.

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 [USCG-2007-0036, formerly CGD07-122] and are available for inspection or copying at United States Coast Guard Sector Miami, 100 MacArthur Causeway, Miami Beach, Florida between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Chris Svencer, United States Coast Guard Sector Miami Waterways Management at 305-535-4550.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On October 22, 2007, we published a notice of proposed rulemaking (NPRM) entitled Anchorage Regulation; Port Everglades, FL in the **Federal Register** (72 FR 59491). We received 10 letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

During the last ten (10) years, nine (9) known vessel groundings and six (6) known vessel anchor mishaps have occurred during attempted or actual use of the Port Everglades anchorage areas. Anchoring mishaps include both misplacement of the anchor itself and/or laying of the anchor chain on the sensitive coral reefs. The east coast of Florida is susceptible to severe and erratic weather, and mariners who are not vigilant can find themselves in extreme situations. Adverse weather conditions, proximity to the reef, congestion in the anchorage, poor navigation and seamanship were contributing factors to the groundings and anchoring mishaps in the Port Everglades anchorage and surrounding vicinity. The current anchorage regulation is published in 33 CFR 110.186. This rule is needed to strengthen existing anchoring requirements and guidelines in order to provide a higher degree of protection to the coastal area and sensitive benthic coral reef ecosystems, as well as to provide a safer anchorage for mariners. This rule re-designates the anchorage areas to account for anchor position and chain lay and limit the amount of time

vessels may remain at anchorage. The Coast Guard has also researched alternative solutions for restructuring the anchorage. These alternatives have included: change nothing and continue to use the current anchorage; create anchorage circles to control the location of vessels in the anchorage; and remove the anchorage completely. The groundings and anchor mishaps have had a negative impact on the sensitive coral reefs and prompts the Coast Guard to alter the current anchorage area. Creating anchorage circles for precision anchorage does not eliminate the threat to the local reefs due to changing weather conditions that may cause vessels, even if properly anchored, to drag over the coral reefs to the west. Lastly, while removing the anchorage altogether would arguably be best for the environment, this option is not economically feasible due to the legitimate need for commercial vessels to anchor while awaiting berth in Port Everglades.

Discussion of Comments and Changes

On October 22, 2007 the Coast Guard published a notice of proposed rulemaking (NPRM) that proposed changing the location of the commercial anchorage located offshore from Port Everglades in Fort Lauderdale, Florida. Ten letters were received in response to the NPRM. All ten letters were in favor of moving the anchorage into deeper waters to protect the environment. Within the ten letters there were numerous different comments addressing the new location of the anchorage.

Three comments addressed moving the anchorage either farther to the south or farther offshore from the Port Everglades main ship channel. Both of these options were extensively explored by the Harbor Safety Committee. Due to a restricted area designated by 33 CFR 334.580, the area south of Port Everglades does not permit anchoring of vessels. This area is immediately south of the main ship channel entrance and continues south for approximately 4 nautical miles. Moving the anchorage further offshore than proposed by this rule creates a potentially untenable and even dangerous situation for many commercial vessels awaiting berths in Port Everglades. The further the vessels are offshore the deeper the water they must anchor in. Beyond the reasonable depth that the revised anchorage proposes, many of the commercial vessels calling on Port Everglades will have insufficient anchor chain to properly scope to the standard 5 to 7 times the water depth to provide sufficient holding, thus presenting a risk

to the reefs, other vessels in the anchorage, and even the vessel deploying their anchor.

Two comments addressed installing a mooring buoy system for vessels in the anchorage. The installation of mooring buoys is extremely costly and once installed require continual maintenance to be effective. One of the comments also addressed funding the buoys by taxing each vessel that uses the port. This option was reviewed and considered by the Harbor Safety Committee but was not a viable option. At this time the committee is unaware of any federal, state, or local government agency willing to authorize, fund, and maintain the mooring buoys. If at a later time a single or joint entity would fund this project, the Harbor Safety Committee would readdress this issue at that time. The solution to move the anchorage offshore to its new location is a step in the right direction to ensure the safety of our reefs and shores.

Another comment addressed better educating mariners regarding the location of the sensitive reefs in the area. In cooperation with the anchorage relocation, the National Oceanic and Atmospheric Administration has added "Co", the charting designation for a coral bottom, on all charts that depict the area offshore of Fort Lauderdale. This in coordination with increased information in the Coast Pilot will assist mariners in understanding the location of reefs in the area.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

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.

This rule may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to utilize the anchorage area outside Port Everglades, Florida. This rule will not have a

significant economic impact on a substantial number of small entities for the same reasons given above in the "Regulatory Evaluation" section of this preamble.

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. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule will have a significant 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.

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. If this rule affects your small business, organization, or governmental jurisdiction and you have questions concerning compliance, please contact Lieutenant Junior Grade Chris Svencer, Coast Guard Sector Miami, Waterways Management Division at (305) 535-4550. 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.

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

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.

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. 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these

standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this rule under Commandant Instruction M16475.1D which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34)(f), of the Instruction, from further environmental documentation.

Under figure 2-1, paragraph (34)(f), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule. Even though a categorical exclusion may be used the Coast Guard found good reason to further investigate the effects the anchorage area modification would have on the environment. A preliminary "Environmental Analysis Check List" is available in the docket where indicated under **ADDRESSES**. Furthermore, as part of section 7 of the Endangered Species Act (50 CFR part 402, 16 U.S.C. 1536), the U.S. Coast Guard opened consultation with a number of stakeholders. The National Oceanic and Atmospheric Administration (NOAA), the National Marine Fisheries Service (NMFS), and U.S. Fish and Wildlife Service (FWS) have reviewed all restructuring plans and believe the proposed action would not likely affect the West Indian Manatee, Johnson's Seagrass, Smalltooth Sawfish, and all local turtle species because the project does not have any elements with the potential to affect these listed species. NOAA also found that the restructuring into deeper waters, farther away from the easternmost reef, is likely to have an indirect beneficial effect on Elkhorn and Staghorn coral by potentially reducing vessel groundings and anchor damage that have adversely affected corals and other important near shore benthic resources in the project area.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

Words of Issuance and Regulatory Text

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071.; 33 CFR 1.05-1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 110.186 by revising paragraphs (a), (b)(3) through (6), and adding paragraphs (b)(7) through (9) to read as follows:

§ 110.186 Port Everglades, Florida.

(a) The anchorage grounds. The anchorage grounds, the center of which is located approximately two and one half miles northeast of the entrance to Port Everglades, is an area bounded by a line connecting points with the following North American Datum 83 coordinates:

Latitude	Longitude
26-08'26.934" N	080-04'28.240" W
26-08'08.560" N	080-04'16.158" W
26-07'56.000" N	080-04'17.486" W
26-07'56.000" N	080-02'42.623" W
26-07'19.500" N	080-02'53.153" W
26-07'19.500" N	080-04'28.800" W
26-06'35.160" N	080-04'28.800" W
26-06'35.160" N	080-04'38.694" W
26-08'26.934" N	080-04'28.240" W

(b) * * *

(3) All vessels within the designated anchorage area shall maintain a 24-hour bridge watch by a licensed deck officer proficient in English, monitoring VHF-FM channel 16. This individual shall confirm that the ship's crew performs frequent checks of the vessel's position to ensure the vessel is not dragging anchor.

(4) Vessels may anchor anywhere within the designated anchorage area provided that: such anchoring does not interfere with the operations of any other vessels currently at anchorage; and all anchor and chain or cable is positioned in such a manner to preclude dragging over reefs.

(5) No vessel may anchor in a "dead ship" status (*i.e.* propulsion or control unavailable for normal operations) without the prior approval of the Captain of the Port. Vessels experiencing casualties such as a main propulsion, main steering or anchoring equipment malfunction or which are

planning to perform main propulsion engine repairs or maintenance, shall immediately notify the Coast Guard Captain of the Port via Coast Guard Sector Miami on VHF-FM Channel 16.

(6) No vessel may anchor within the designated anchorage for more than 72 hours without the prior approval of the Captain of the Port. To obtain this approval, contact the Coast Guard Captain of the Port, via the Port Everglades Harbor Master, on VHF-FM Channel 14.

(7) The Coast Guard Captain of the Port may close the anchorage area and direct vessels to depart the anchorage during periods of adverse weather or at other times as deemed necessary in the interest of port safety or security.

(8) Commercial vessels anchoring under emergency circumstances outside the anchorage area shall shift to new positions within the anchorage area immediately after the emergency ceases.

(9) Whenever the maritime or commercial interests of the United States so require, the Captain of the Port, U.S. Coast Guard, Miami, Florida, may direct relocation of any vessel anchored within the anchorage area. Once directed, such vessel must get underway at once or signal for a tug, and must change position as directed.

Dated: January 10, 2008.

D.W. Kunkel,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. E8-1757 Filed 2-4-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2008-0013]

RIN 1625-AA87

Security Zone; MacDill Air Force Base, Tampa Bay, FL

AGENCY: Coast Guard, DHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Coast Guard is establishing a security zone that is concurrent with the Army Corps of Engineers restricted area adjacent to MacDill Air Force Base. The security zone is necessary to facilitate security operations conducted at the Air Force Base. All persons, vessels, or other craft are prohibited from anchoring, mooring, drifting, or transiting within this zone, unless authorized by the Captain of the

Port St. Petersburg or a designated representative.

DATES: This interim rule is effective February 5, 2008. Comments and related material must reach the Docket Management Facility on or before April 7, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG-2008-0013 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* 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.

(3) *Hand delivery:* Room W12-140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Waterways Management Division, Sector St. Petersburg, FL (813) 228-2191, Ext 8307. 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:

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. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2008-0013), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have