is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of McDonnell Douglas Alert Service Bulletin DC10–71A159, Revision 1, dated January 31, 1995, was approved previously by the Director of the Federal Register as of November 10, 1999 (64 FR 54202, October 6, 1999).

(3) Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(g) This amendment becomes effective on September 25, 2001.

Issued in Renton, Washington, on August 13, 2001.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–20804 Filed 8–20–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address for Orion Corp. ORION-FARMOS.

DATES: This rule is effective August 21, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Orion Corp. ORION-FARMOS, P.O. Box 425, SF–20101 Turku, Finland, has informed FDA of a change of sponsor's name and address to Orion Corp., Orionintie 1, 02200 Espoo, Finland. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's name and address.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is 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. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Orion Corp. ORION-FARMOS'' and in the table in paragraph (c)(2) by revising the entry for ''052483'' 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
* * * * * * *	
Orion Corp., Orionintie 1, 02200 Espoo, Finland	052483
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
052483	Orion Corp., Orionintie 1, 02200 Espoo, Finland
* * * * * * *	

Dated: July 31, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 01–20982 Filed 8–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ponazuril

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Bayer Corp., Agriculture Division, Animal Health. The NADA provides for veterinary prescription use of ponazuril

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.

[FR Doc. 01–20983 Filed 8–20–01; 8:45 am]

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