is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace area extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Salyer Farms, CA [Revised]

Salyer Farms Airport, CA
(Lat. 36°05′20″ N, long. 119°32′33″ W)
Salyer Farms RBN
(Lat. 36°05′05″ N, long. 119°32′43″ W)
El Rico Airport, CA
(Lat. 36°02′45″ N, long. 119°38′48″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Salyer Farms Airport and within 2 miles each side of the 151° bearing from the Salyer Farms Radio Beacon extending from the 6.6-miles radius to 8.3 miles southeast of the Salyer Farms Radio Beacon, excluding that airspace with a 1-mile radius of El Rico Airport.

* * * * *

Issued in Lost Angeles, California on July 17, 1997.

Sabra W. Kaulia,

Assistant Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 97–21042 Filed 8–8–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin Gel

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 Fort Dodge Animal Health. The NADA provides for oral use of moxidectin gel for horses and ponies for treatment and control of infections of certain gastrointestinal parasites.

EFFECTIVE DATE: August 11, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth Street NW., P.O. Box 518, Fort Dodge, IA 50501, filed original NADA 141–087 that provides for use of Quest™ moxidectin 2 percent oral gel in horses and ponies at 0.4 milligram moxidectin per kilogram of body weight for treatment and control of infections of certain large strongyles, small strongyles (adult and larvae), encysted cyathostomes, ascarids, pinworms, hairworms, large-mouth stomach worms, and horse stomach bots, and for supression of small strongyle egg production for 84 days. The NADA is approved as of July 11, 1997, and the regulations are amended by adding new 21 CFR 520.1452 to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for 3 years of marketing exclusivity beginning July 11, 1997, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.1452 is added to read as follows:

§ 520.1452 Moxidectin gel.

(a) *Specifications.* The gel contains 2 percent moxidectin (20 milligrams per milliliter).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 0.4 milligram moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* Horses and ponies for treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated lumenal larvae); encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris equi* (adults and L4 larval stages)), hairworms (*Trichostrongylus axei* (adults)), large-

mouth stomach worms (*Habronema muscae* (adults)), and horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars)). One dose also supresses small strongyle egg production for 84 days.

(3) *Limitations.* For horses and ponies including breeding mares and stallions. Not for use in horses and ponies intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: August 1, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–21086 Filed 8–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 772

[FHWA Docket No. 96–26: FHWA–97–2348]

RIN 2125–AD97

Procedures for Abatement of Highway Traffic Noise and Construction Noise

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is adopting, as final, a current interim final rule that revises the FHWA regulation that allows Federal participation for Type II noise abatement projects—that is, proposed Federal or Federal-aid highway projects for noise abatement on an existing highway. This final rule restricts Federal participation for Type II projects to those that were approved before the date of enactment of the National Highway System Designation Act of 1995 (NHS) (Pub. L. 104–59, 109 Stat. 605) or are proposed along lands that were developed or were under substantial construction before approval of the acquisition of the rights-of-way for, or construction of, an existing highway.

EFFECTIVE DATE: September 30, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Armstrong, Office of Environment and Planning, (202) 366–2073, or Mr. Robert Black, Office of the Chief Counsel, (202) 366–1359, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: On August 29, 1996, the FHWA published an interim final rule along with a request for comments in the **Federal Register** (61 FR 45319) as a means of implementing changes in 23 CFR part 772 for Type II project eligibility. The interim rule prohibits Federal participation in Type II projects unless development predated the existence of any highway.

Discussion of Comments

The public comment period for the interim final rule closed on November 27, 1996. The FHWA received two comments from the Illinois Department of Transportation. The response concerning this interim final rule is available for review at the U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590.

The first comment noted that the FHWA went beyond the changes called for by the NHS Act by indicating that ''[n]oise abatement measures will not be approved at locations where such measures were previously determined not to be reasonable and feasible for a Type I project.'' The comment stated that there is no basis in the NHS legislation for this change and questioned the appropriateness of ruling out the possibility of FHWA participation in a Type II project on this basis.

It was the intent of the NHS legislation to prohibit Federal participation in the construction of Type II noise barriers in instances where proper consideration has not been given to highway traffic noise concerns and issues during the local growth and development process, *i.e.*, growth and development has occurred after a highway was constructed and has created unmitigated traffic noise impacts. This intent was meant to limit Federal expenditures for Type II noise barriers.

The questioned statement is meant to place increased emphasis on the importance of noise-compatible land use planning at the State and local level. Highway traffic noise should be reduced through a program of shared responsibility. Thus, the FHWA encourages State and local governments to practice compatible land use planning and control in the vicinity of highways. Local governments should use their power to regulate land development in such a way that either noise-sensitive land uses are prohibited from being located adjacent to a highway, or developments are planned, designed, and constructed to minimize noise impacts. The challenged statement has been left unchanged.

The second comment noted that, while the NHS legislation specifically refers to limiting Federal participation in the construction of Type II noise barriers, revised § 772.13 limits Federal participation in ''noise abatement measures,'' a broader term that exceeds the clear language of the NHS legislation. As was the case above, the wording ''noise abatement measures'' in revised § 772.13 was used to meet the intent of the NHS legislation to generally prohibit Federal Type II expenditures in instances where proper consideration has not been given to highway traffic noise concerns and issues during the local growth and development process. Therefore, no change has been made in the final rule.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the Department of Transportation Regulatory Policies and Procedures. The amendment clarifies some of the requirements for Federal participation in noise abatement projects for the 17 States that have constructed at least one Type II noise barrier. It is anticipated that the economic impact of the rulemaking will be minimal; therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Based on the evaluation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. The amendment deals only with the eligibility of certain State highway noise abatement projects for Federal participation. As such, it affects only State highway agencies and not small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. It does not impose any new obligation or requirement on a State. It does not affect the amount of Federal transportation funds that go to a State. A State is not required to have a Type II Noise Program. A State may still expend its own funds on a noise abatement project.