DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 308, 310, 320, 327, 381, 416, and 417

[Docket No. 97–047N]

Availability of Guidelines for Escherichia coli Testing

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability of revised guidelines.

SUMMARY: The Food Safety and Inspection Service (FSIS) has made revisions to the ''Guidelines for *Escherichia coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments'' (*E. coli*-1) and ''Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments'' (*E. coli*-2). The revised guidelines are available from FSIS.

ADDRESSES: Copies of the guidebooks are available from the Public Outreach Office, Room 1180, South Agriculture Building, 1400 Independence Avenue, SW, Washington, DC 20250–3700. To obtain a copy, please mail your request indicating the number (i.e., *E. coli*-1 or *E. coli*-2) and title of the document to the Public Outreach Office at the above address; or FAX to (202) 720–9063.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Stolfa, Assistant Deputy Administrator, Regulations & Inspection, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service at (202) 205–0699, FAX (202) 401–1760.

SUPPLEMENTARY INFORMATION: On July 25, 1996, FSIS published a final rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' (61 FR 38806). The new regulations (1) require that each establishment develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOP's); (2) require regular microbial testing for generic *E. coli* by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Points).

As appendices to the final rule, FSIS included guidelines for *E. coli* testing. These guidelines outline the sampling and microbial testing procedures that would meet the regulatory requirements and may be helpful to microbiologists or analytic laboratories.

On May 13, 1997, FSIS published the final rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,'' (62 FR 26211). In light of some revisions to the *E. coli* testing requirements, FSIS has revised the guidelines. The new guidelines, ''Guidelines for *Escherichia coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments' (*E. coli*-1) and ''Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments'' (*E. coli*-2), are available from FSIS (see **ADDRESSES**).

Done at Washington, DC, on: August 7, 1997.

Thomas J. Billy,

Administrator.

[FR Doc. 97–21123 Filed 8–8–97; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–AWP–33]

Amendment to Class E Airspace; Salyer Farms, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace area at Salyer Farms, CA. The development of a Special Global Positioning System (GPS) Runway (RWY) 32 Standard Instrument Approach Procedure (SIAP) has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Salyer Farms Airport, Salyer Farms, CA.

EFFECTIVE DATE: 0901 UTC September 11, 1997.

FOR FURTHER INFORMATION CONTACT: Larry Tonish, Airspace Specialist, Airspace Branch, AWP–520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6555.

SUPPLEMENTARY INFORMATION:

History

On June 9, 1997, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at Salyer Farms, CA (62 FR 31371). This action will provided adequate controlled airspace to accommodate the Special GPS RWY 32 SIAP at Salyer Farms Airport, Salyer Farms, CA.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace area at Salyer Farms, CA. The development of a Special GPS SIAP has made this action necessary. The intended effect of this action is to provide adequate airspace for aircraft executing the Special GPS RWY 32 SIAP at Salyer Farms Airport, Salyer Farms, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1)

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-