effective September 16, 2004, is amended as follows:

* * * * *

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

AGL MN E5 Tracy, MN [New]

Tracy Municipal Airport, MN
(Lat. 44°14′57″ N., long. 95°36′26″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Tracy Municipal Airport.

* * * * *

Issued in Des Plaines, Illinois, on March 11, 2005.

Nancy B. Kort,

Area Director, Central Terminal Operations.

[FR Doc. 05–6654 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 558

New Animal Drugs; Limitations of Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the limitations to conditions of use for products approved under 22 new animal drug applications (NADAs) and 5 abbreviated new animal drug applications (ANADAs). In error, a label statement warning against the use of these products in calves to be processed for veal was not codified at the time supplemental NADAs or ANADAs were approved. FDA is also amending the animal drug regulations to reflect the approved preslaughter withdrawal periods and milk withholding period in cattle following use of penicillin G procaine aqueous suspension. This action is being taken to improve the accuracy of the animal drug regulations.

DATES: This rule is effective April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Jeffrey Punderson, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4109, e-mail: *jpunders@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Over the past decade, FDA's Center for Veterinary Medicine (CVM) asked sponsors of certain products approved for use in cattle to place this warning on their labels: ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' This was done to reduce the frequency of unsafe residues of animal drugs in veal. While many sponsors complied and filed applications to change their labels, CVM did not always codify this limitation to approved conditions of use when the supplemental application was approved. At this time, FDA is amending the animal drug regulations to reflect the limitations to conditions of use for the following products:

Application No.	21 CFR Section	Trade Name
NADA 011–060	520.1660c	TERRAMYCIN Scour Tablets
NADA 012–350	558.55	AMPROVINE 25%; AMPROL 25%
NADA 012–350	520.100c	CORID 1.25% Crumbles
NADA 012–965	522.2640a	TYLAN Injection 50 mg; TYLAN Injection 200 mg
NADA 013–149	520.100a	CORID 9.6% Solution
NADA 030–434	520.540a	AZIUM Powder
NADA 030–435	520.540b	AZIUM Boluses 10 mg
NADA 031–715	520.2220b	ALBON; AGRIBON Boluses–2.5, -5.0, and -15.0
NADA 033–127	520.2200a	PRINZONE, PYRADAN, and VETISULID Boluses
NADA 033–165	520.100b	CORID 20% Soluble Powder
NADA 033–373	520.2200b	PRINZONE, PYRADAN, and VETISULID Powder
NADA 033–318	522.2200	PRINZONE, PYRADAN, and VETISULID Injection
NADA 041–245	522.2220	AGRIBON Injection 40%; ALBON
NADA 065–010	522.1696b	AGRICILLIN Pen Aqueous; AQUA-CILLIN; Penicillin G Co-op
NADA 065–110	522.1696b	PRO-PEN G in Aqueous Suspension
NADA 065–140	520.2345d	TET-SOL 10 and TET-SOL 324
NADA 065–269	520.2345d	POLYOTIC Soluble Powder
NADA 065–441	520.2345d	POLYOTIC Soluble Powder Concentrate
NADA 065–493	522.1696b	Penicillin G Procaine Aqueous Suspension
NADA 065–496	520.2345d	Tetracycline Soluble Powder

Application No.	21 CFR Section	Trade Name
NADA 093–107	520.2220b	ALBON S.R.
NADA 138–955	522.2640a	Tylosin Injection
NADA 141–002	520.1660c	OXY 500 and 1000 Calf Boluses
ANADA 200–038	522.2220	DI-METHOX Injection 40%; Sulfadimethoxine Injection 40%
ANADA 200–049	520.2345d	TETRA-BAC 324 Soluble Powder; Tetracycline Hydrochloride Soluble Powder–324.
ANADA 200–136	520.2345d	Tetracycline HCL Powder; Tetracycline Hydrochloride Soluble Powder–324.
ANADA 200–177	522.2220	Sulfadimethoxine Injection 40%
ANADA 200–234	520.2345d	TETRASOL Soluble Powder

Accordingly, the agency is amending the regulations in 21 CFR 520.100a, 520.100b, 520.100c, 520.540a, 520.540b, 520.1660c, 520.2200a, 520.2200b, 520.2220b, 520.2345d, 522.1696b, 522.2200, 522.2220, 522.2640a, and 558.55.

In addition, FDA has found that the animal drug regulations do not reflect the approved preslaughter withdrawal period for cattle, sheep, and swine for PRO–PEN G in Aqueous Suspension sponsored by Phoenix Scientific, Inc., approved under NADA 065–110. FDA has also found that the animal drug regulations do not reflect the approved milk withholding period for Penicillin G Procaine Aqueous Suspension sponsored by G.C. Hanford Manufacturing Co. (NADA 065–493) and AGRICILLIN Pen Aqueous, AQUA–CILLIN, and Penicillin G Co-op sponsored by Norbrook Laboratories Ltd. (NADA 065–010). At this time, the regulations are being amended in 21 CFR 522.1696b to correct these errors.

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

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 parts 520, 522, and 558 are 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.

§ 520.100a [Amended]

■ 2. Section 520.100a is amended in paragraphs (d)(2)(i)(*b*) and (d)(2)(ii)(*b*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.100b [Amended]

■ 3. Section 520.100b is amended in paragraphs (d)(1)(ii) and (d)(2)(ii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.100c [Amended]

■ 4. Section 520.100c is amended in paragraphs (d)(1)(ii) and (d)(2)(ii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.540a [Amended]

■ 5. Section 520.540a is amended in paragraph (c)(4) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.540b [Amended]

■ 6. Section 520.540b is amended in paragraph (a)(3)(vi) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.1660c [Amended]

■ 7. Section 520.1660c is amended in paragraph (d)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2200a [Amended]

■ 8. Section 520.2200a is amended in paragraph (e)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2200b [Amended]

■ 9. Section 520.2200b is amended in paragraph (e)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2220b [Amended]

■ 10. Section 520.2220b is amended in paragraph (d)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2345d [Amended]

■ 11. Section 520.2345d is amended in paragraph (d)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 12. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 13. Section 522.1696b is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations*. Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 053501 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 010515, 055529, and 059130: Treatment should not exceed 4 consecutive days. Discontinue treatment for the following number of days before slaughter: Cattle—10; sheep—9; and swine—7. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 522.2200 [Amended]

■ 14. Section 522.2200 is amended in paragraph (e)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 522.2220 [Amended]

■ 15. Section 522.2220 is amended in paragraph (a)(3)(iii)(*c*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 522.2640a [Amended]

■ 16. Section 522.2640a is amended in paragraph (e)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.55 [Amended]

■ 18. Section 558.55 is amended in paragraphs (d)(1)(i)(*b*) and (d)(1)(ii)(*b*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

Dated: March 25, 2005.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 05–6518 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–262F]

Schedules of Controlled Substances: Placement of Zopiclone Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, zopiclone, including its salts, isomers and salts of isomers into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of zopiclone and products containing zopiclone.

DATES: *Effective Date:* April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Christine Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION: Zopiclone is a central nervous system depressant drug. On December 15, 2004, the Food and Drug Administration (FDA) approved (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone, for marketing under the trade name Lunesta TM. Eszopiclone will be marketed as a prescription drug product for the treatment of insomnia.

On January 18, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a letter recommending that zopiclone and its isomers be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the January 18, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Zopiclone and its Optical Isomers in Schedule IV of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

The correspondence from the Acting Assistant Secretary for Health to DEA dated January 18, 2005, confirmed that FDA approved the New Drug Application (NDA) for eszopiclone and issued an approval letter to the NDA sponsor on December 15, 2004. After a review of the available data, including the DHHS recommendation, the Deputy Administrator of the DEA, in a February 14, 2005, **Federal Register** notice of proposed rulemaking (70 FR 7449), proposed placement of zopiclone into Schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before March 16, 2005.

Comments Received

DEA received one comment in response to this notice of proposed rulemaking. The commenter stated that the current federal regulations governing the process of drug control and approval are excessive and are interfering with the practice of medicine.

DEA disagrees. The Controlled Substances Act contains specific mandates pertaining to the scheduling of controlled substances. DEA has followed all of those mandates regarding the scheduling of zopiclone, including receiving from the Secretary of DHHS a scientific and medical evaluation, and recommendation, regarding control (21 U.S.C. 811(b)); considering the factors enumerated in 21 U.S.C. 811(c); determining, based on the above, appropriate scheduling for zopiclone (21 U.S.C. 812(b)); and conducting a formal rulemaking to schedule zopiclone (21 U.S.C. 811(a)). In no way does this scheduling action interfere with the practice of medicine.

Scheduling of Zopiclone

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in