List of Subjects in 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

2. Section 558.265 is amended by adding paragraphs (c)(1)(viii) and (c)(3)(ii) to read as follows:

§ 558.265 Halofuginone hydrobromide.

* * * * *

(c) * * *

(1) * * *

(viii) *Amount per ton*. Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

* * * * *

(3) * * *

(ii) *Amount per ton*. Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

3. Section 558.530 is amended by revising paragraphs (a) and (d)(5) and by removing paragraph (d)(6) to read as follows:

§ 558.530 Roxarsone.

(a) *Approvals*. Type A medicated articles: 10, 20, 50, and 80 percent to 046573 in § 510.600(c) of this chapter for use as in paragraphs (d)(1) through (d)(4) of this section.

* * * * *

(d) * * *

(5) *Permitted combinations*. It may be used in accordance with this section in combination with:

(i) Aklomide as in § 558.35.

(ii) Amprolium as in § 558.55.

(iii) Amprolium and ethopabate as in § 558.58.

(iv) Bacitracin methylene disalicylate as in § 558.76.

(v) Bacitracin zinc as in § 558.78.

(vi) Bambermycins and bambermycins plus certain anticoccidials as in § 558.95.

(vii) Chlortetracycline as in § 558.128.

(viii) Clopidol as in § 558.175.

(ix) Decoquinate alone or in combination as in § 558.195.

(x) [Reserved]

(xi) Halofuginone alone or in combination as in § 558.265.

(xii) Lasalocid alone or in combination as in § 558.311.

(xiii) Monensin alone or in combination as in § 558.355.

(xiv) Narasin alone or in combination as in § 558.363.

(xv) Nequinate as in § 558.365.

(xvi) Nicarbazin alone or in combination as in § 558.366.

(xvii) Nitromide and sulfanitran as in § 558.376.

(xviii) Penicillin and zoalene as in § 558.680.

(xix) Robenidine hydrochloride as in § 558.515.

(xx) Salinomycin alone or in combination as in § 558.550.

(xxi) Semduramicin alone or in combination as in § 558.555.

(xxii) Sulfadimethoxine, ormetoprim as in § 558.575.

(xxiii) Zoalene alone or in combination as in § 558.680.

Dated: July 17, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–18744 Filed 7–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[DEA–190I]

RIN 1117–AA54

Facsimile Transmission of Prescriptions for Patients Enrolled in Hospice Programs

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim rule.

SUMMARY: DEA is amending Title 21, Code of Federal Regulations (CFR) 1306.11(g) to clearly include articulate that prescriptions for Schedule II narcotic substances for patients enrolled in hospice care certified by Medicare under Title XVIII or licensed by the state may be transmitted by facsimile. The regulation as it is currently worded grants this allowance for Schedule II prescriptions for patients ''residing in a hospice * * *''. This phrase has been perceived by the regulated industry as requiring that the patient reside in a hospice facility to the exclusion of other care settings, such as home hospice care. It was never DEA's intent to omit the significant number of patients receiving hospice care who reside at home. This interim rule clarifies DEA regulations in response to industry questions.

DATES: *Effective Date:* July 25, 2000.

Comments: Written comments must be submitted on or before September 25, 2000.

ADDRESSES: Comments should be submitted in triplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

What Do DEA Regulations Currently Provide?

DEA regulations permit a pharmacy to dispense a Schedule II narcotic substance pursuant to a prescription transmitted to the pharmacy via facsimile for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state (21 CFR 1306.11(g)). The faxed prescription

serves as the original prescription for recordkeeping purposes. However, the use of the language ''residing in a hospice certified by Medicare under Title XVIII or licensed by the state'' has been perceived by the regulated industry as requiring that the patient reside in a hospice facility to the exclusion of other care settings, such as home hospice care. DEA has received letters from home hospice care providers inquiring about the requirements for facsimile transmission of Schedule II prescriptions for their patients. It was never DEA's intent to create an exclusion for these patients. DEA regulations were meant to cover all patients enrolled in hospice programs certified by Medicare under Title XVIII or licensed by the state, regardless of where the patient resides. Consistent with DEA's interpretation of its regulations, DEA has responded to the inquiries it has received with letters stating that its regulations allow for facsimile transmission of prescriptions to such patients.

What Change Does This Rulemaking Make?

The inquiries DEA has received indicate that the use of the term ''residing'' did not fully convey DEA's intended result. Therefore, DEA is modifying the language of 21 CFR 1306.11(g) to clarify that the permission for facsimile transmission of Schedule II narcotic prescriptions covers all patients enrolled in hospice programs certified by Medicare under Title XVIII or licensed by the state.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

This rule is minor and technical in nature, merely clarifying existing DEA regulations and requirements, the intent of which was clearly indicated in the original notices. Further, to the extent that regulated parties were following a more restrictive interpretation of existing regulations, the clarification this rule makes lessens a perceived regulatory restriction to the benefit of Medicare-certified or state licensed hospice program patients needing Schedule II narcotic substances. The original rulemakings (proposed rule 61 FR 8503, DEA–139P, RIN 1117–AA33; final rule 62 FR 13938, DEA–139F, RIN 1117–AA33) clearly indicate that DEA's intent was to permit the facsimile transmission of Schedule II prescriptions for all patients enrolled in hospice programs, regardless of where the patient resides. This interim rule does not change DEA practice or policy. Rather, the regulations are being amended to more accurately reflect DEA's intention in the rule promulgated at 62 FR 13938 and to alleviate public confusion. Accordingly, DEA finds good cause to exempt this rule from the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and delay in effective date.

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in a manner consistent with the principles of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). It will not have a significant economic impact on a substantial number of small business entities. This rulemaking clarifies the regulations regarding the facsimile transmission of prescriptions for Schedule II narcotic substances for patients enrolled in hospice programs.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866, Section 1(b). DEA has determined that this is not a significant rulemaking action. This rulemaking clarifies the regulations regarding the facsimile transmission of prescriptions for Schedule II narcotic substances for patients enrolled in hospice programs. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7297.

List of Subjects in 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, 21 CFR part 1306 is amended to read as follows:

PART 1306—[AMENDED]

1. The authority citation for Part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b).

2. Section 1306.11 is amended by revising paragraph (g) to read as follows:

§ 1306.11 Requirement of prescription.

* * * * *

(g) A prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h).

Dated: July 14, 2000.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 00–18572 Filed 7–24–00; 8:45 am]

BILLING CODE 4410–09–M